SCIENCE AND MISSION AT RISK: FDA'S SELF-ASSESSMENT

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

JANUARY 29, 2008

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SUBMITTED MATERIAL

SCIENCE AND MISSION AT RISK: FDA'S SELF-ASSESSMENT

TUESDAY, JANUARY 29, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123 of the Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Members present: Representatives Stupak, DeGette, Melancon, Waxman, Green, Schakowsky, Inslee, Dingell (ex officio), Shimkus, Walden, Murphy, Burgess, Blackburn and Barton (ex officio).

Staff present: Chris Knauer, Keith Barstow, Scott Schloegel, John Sopko, Angela Davis, Kyle Chapman, Alan Slobodin, Peter Spencer, and Whitney Drew.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. This meeting will come to order.

Today we have a hearing entitled "Science and Mission At Risk: FDA's Self-Assessment." Each member will be recognized for a 5-minute opening statement. I will begin.

Since the Federal Food, Drug and Cosmetic Act was first enacted in 1938, the FDA's role in protecting American consumers has expanded considerably. The FDA is now responsible for ensuring the safety of medical devices, human food, animal feed additives, new human and animal drugs, human biological products, the list goes on. Today, no new pharmaceutical product or medical technology can be used in the United States without the FDA first determining that it is safe and effective for its intended use. By some estimates, the agency now regulates more than $1 trillion in consumer products or close to 25 cents of every U.S. dollar spent. Unfortunately, as this committee under both Republican and Democratic leadership has documented, FDA's resources have become wholly inadequate, given the agency's expansive mission. Accordingly, the agency's ability to protect American families from unsafe food, drugs, medical devices and other products has radically deteriorated. Last year's slew of tainted consumer goods and related recalls were the proverbial canary in the coalmine, illustrating the strain under which the FDA now functions.

To his credit, in 2006 FDA Commission Andrew von Eschenbach requested the FDA's Science Board, which is his primary advisory group, which is made up of a special subcommittee, to assess

whether science and technology at the agency is capable of supporting existing and future regulatory operations. The subcommittee had extensive input from 30 world-class external advisors representing industry, academia and other government agencies. These experts were selected based on their extensive knowledge of cutting-edge research, budget, science and management operations. Their assessments were compiled in a report entitled "FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology." All 33 advisors and subcommittee members signed off on the findings of this report and was presented to the FDA last month and unanimously accepted by the Science Advisory Board.

Today we have the honor and privilege to hear directly from the chair of the Science Board subcommittee as well as from a number of its expert advisors. They will raise a number of concerns regarding FDA's current capability. More directly, they will raise their concern that the FDA's overall mission of protecting public health is at risk. The report's findings are shocking and extensive. Some key concerns include the following.

The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organization structure is weak. It does not have the capacity to ensure the safety of the Nation's food supply furthermore. The FDA's ability to provide basic inspections, conduct key rulemaking and carry out enforcement actions are severely eroded as is its ability to respond to food-related outbreaks in a timely manner. During the past 35 years the decrease in FDA funding has forced the agency to impose a 78 percent reduction in food inspections. The FDA cannot fulfill many of its core regulatory functions because its IT infrastructure is obsolete, unstable and inefficient. The agency faces substantial employee recruitment and retention challenges. The agency has insufficient access to clinical data needed for various core missions and thus cannot effectively regulate products based on new science, and this list goes on and on.

Alone, each one of these issues would be a daunting task to resolve. Taken together, they suggest much of the FDA's core regulatory mission is at risk. When coupled with the recent findings by the Government Accountability Office (GAO) regarding the agency's effort to inspect food, foreign-made drugs and medical devices, the situation is truly alarming. As pointed out in the GAO report, American lives are now at risk.

The findings of this report, however, should come as little surprise to members of this subcommittee. The work we conducted last year provides ample evidence that FDA is increasingly struggling to perform its most rudimentary regulatory mission. For example, the subcommittee held four hearings last year related to how FDA protects Americans against substandard foods. These were prompted because of incidents involving tainted human and pet food and other commodities. FDA's failed regulation of domestic food producers, its ill-conceived plan to close laboratories and reorganize field staff and its inability to ensure the safety of imported foods from China and other foreign markets painted a bleak picture of FDA's ability to protect the Nation's food supply.

In addition to our food safety investigations, the subcommittee examined FDA's foreign drug inspection program. The investigation found FDA's IT system for managing drug imports and related inspections was antiquated and disturbingly incapable of providing timely and basic data. Because of resource constraints on field inspectors and related travel, FDA could only inspect about 7 percent of all foreign establishments in any given year. Experts told the subcommittee that foreign drug firms should be inspected at least once every few years but at that rate it would take the FDA 13 years to inspect each foreign establishment for one time.

Today GAO will report similar findings relating to FDA's ability to inspect foreign medical device manufacturers. One of the key findings of the Science Advisory Board report is that, and I quote, "In contrast to previous reviews warned crisis would arise if funding issues were not addressed. Recent events and our findings indicate that some of those crises are now realities and American lives are at risk." These observations are troubling and they fit a pattern. FDA is increasingly being asked to do more and more with less and less and many of the agency's tools and resources are stretched to the breaking point and incapable of supporting the agency's mission.

I would like to thank the witnesses who will be testifying today. Your work has assisted the committee greatly and we look forward to your continued help and leadership. The committee takes the reports and your findings very, very seriously. The deterioration of the FDA's ability to protect the American people did not happen overnight. This deterioration is like a cancer that has developed over many years under the watch of both Republican and Democratic administrations. This deterioration is also not something that will be changed overnight, but there are many recommendations in the Science Advisory Board report that can be addressed immediately.

The FDA and Congress have an opportunity for great leadership. It is my sincere hope that Commissioner von Eschenbach will commit to us that he will not just accept the startling findings and the positive recommendations made by the Science Advisory Board but that he will develop and implement the Science Advisory Board and GAO recommendations to put the agency back on track as the world's premiere agency to safeguard food and drugs.

The Commissioner should know that Congress is not willing to throw more money at the problem. We will require a realistic plan with vision and measurable results to ensure the promises made are commitments kept. The Commissioner has taken the first step in developing a plan by asking for this report. He has also shown a willingness to listen and learn from our hearings. Just last week he announced that he will implement one of our key recommendations from last fall's hearing on drug imports. The FDA plans to open offices in foreign countries such as China and India where so much of our food and drugs now come from. This is an important small step. With required follow-through and oversight it can be a positive step. I look forward to working with the Commissioner on how he can forge ahead to give the FDA the tools necessary to protect the American public. Our Nation deserves nothing less.

[The prepared statement of Mr. Stupak follows:]

STATEMENT OF HON. BART STUPAK

Since the Federal Food, Drug, and Cosmetic Act was first enacted in 1938, FDA's role in protecting the American consumer has expanded considerably. FDA is now responsible for ensuring the safety of medical devices, human food, animal feed additives, new human and animal drugs, human biological products, and the list goes on. Today, no new pharmaceutical product or medical technology can be used in the U.S. without FDA first determining that it is safe and effective for its intended use. By some estimates, the agency now regulates more than $1 trillion in consumer products or close to 25 cents of every U.S. consumer dollar spent.

Unfortunately, as this Committee under both Republican and Democratic leadership has documented, FDA's resources have become woefully inadequate given the agency's expansive mission. Accordingly, the agency's ability to protect American families from unsafe foods, drugs, medical devices, and other products has radically deteriorated. Last year's slew of tainted consumer goods and related recalls was the proverbial canary-in-the-coal-mine illustrating the strain under which the FDA now functions.

To his credit, in December 2006, FDA Commissioner Andrew von Eschenbach requested that the FDA Science Board-which is his primary advisory group-form a special subcommittee to assess whether ″science and technology″ at the agency is capable of supporting existing and future regulatory operations.

The subcommittee had extensive input from 30 world class external advisors representing industry, academia, and other government agencies. These experts were selected based on their extensive knowledge of cutting-edge research, budget, science, and management operations. Their assessments were compiled in a report entitled, ″FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology.″ All 33 advisors and subcommittee members signed off on the findings of this report, which was presented to FDA last month and unanimously accepted by the Science Advisory Board.

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- The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak;
- The FDA does not have the capacity to ensure the safety of the Nation's food supply;
- The FDA's ability to provide basic inspections, conduct key rulemakings, and carry out enforcement actions are severely eroded, as is its ability to respond to food-related outbreaks in a timely manner;
- During the past 35 years, the decrease in FDA funding has forced the agency to impose a 78 percent reduction in food inspections;
- The FDA cannot fulfill many of its core regulatory functions because its IT infrastructure is obsolete, unstable, and inefficient;
- The agency faces substantial employee recruitment and retention challenges;
- The agency has insufficient access to critical data needed for various core missions and thus cannot effectively regulate products based on new science;

And the list goes on.

Alone, each of these issues would be a daunting task to resolve. Taken together, they suggest much of FDA's core regulatory mission is at risk. When coupled with the recent findings by the Government Accountability Office (GAO) regarding the agency's effort to inspect food, foreign-made drugs, and medical devices, the situation is truly alarming. As pointed out in the GAOreport, ″American lives are now at risk.″

The findings of this report, however, should come as little surprise to Members of this Subcommittee. The work we conducted last year provides ample evidence that FDA is increasingly struggling to perform its most rudimentary regulatory missions.

For example, the Subcommittee held four hearings related to how FDA protects Americans against substandard foods. These were prompted because of incidents involving tainted human and pet food and other commodities. FDA's failed regulation of domestic food producers, its ill-conceived plan to close laboratories and reorganize field staff, and its inability to ensure the safety of imported foods from China and other foreign markets, painted a bleak picture of FDA's ability to protect the Nation's food supply.

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One of the key findings in the Science Advisory Board's report is that ″In contrast to previous reviews that warned crises would arise if funding issues were not addressed, recent events and our findings indicate that some of those crises are now realities and American lives are at risk.″ These observations are troubling and they fit a pattern: FDA is increasingly being asked to do more and more with less and less and many of the agency's tools and resources are stretched to the breaking point and incapable of supporting the agency's mission.

I would like to thank the witnesses who will be testifying today. Your work has assisted this Committee greatly, and we look forward to your continued help and leadership. The Committee takes the report's findings very seriously.

The deterioration of the FDA's ability to protect the American people did not happen over night. This deterioration is a cancer that has developed over many years, under the watch of both Republican and Democratic Administrations. This deterioration is also not something that will be changed over night, but there are many recommendations in the Science Advisory Board's report that can be addressed immediately.

The FDA - and Congress - have an opportunity for great leadership. It is my sincere hope that Commissioner von Eschenbach will commit to us that he will not just accept the startling findings and the positive recommendations made by the Science Advisory Board, but he will develop and implement the Science Board and GAO's recommendations to put the agency back on track as the world's premier agency to safeguard food and drugs. The Commissioner should know, that Congress is not willing to just throw more money at the problem. We will require a realistic plan with vision and measurable results to ensure the promises made are commitments kept.

The Commissioner has taken the first step in developing a plan by asking for this report. He has also shown a willingness to listen and learn from our hearings. Just last week he announced that he will implement one of our key recommendations from last fall's hearing on drug imports. The FDA plans to open offices in foreign countries such as China and India, where so much of our food and drugs now come from. This is an important small step - with required follow through - and oversight.

I look forward to working with the Commissioner on how we can forge ahead to give the FDA the tools necessary to protect the American public. Our Nation deserves nothing less.

Mr. STUPAK. I would next turn to my friend, the ranking member, Mr. Shimkus from Illinois, for an opening statement, please.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you, Mr. Chairman.

Today's hearing will focus on the findings and recommendations by the special subcommittee of the Food and Drug Administration's Science Advisory Board, which sought to review the state of science at the FDA, and I appreciate your attendance and your work.

As we will hear this morning from some of the report's distinguished authors, the ability of the agency to carry out its various missions to protect the public health has severely deteriorated over the past 2 decades. This has occurred because more has been asked and required of the agency over the years without the requisite resources provided to do the job. As we will hear, the report does not paint a pretty picture. This report makes the case for strengthening the FDA in very sobering language. We will hear about obso-

lete information networks, failures of planning, the draining of science talent, loss of key managers, and that Congress has enacted more than 100 statutes with little added funding. These findings are troubling but not surprising.

We know from this subcommittee's own investigation that there are serious shortcomings in FDA's ability to manage and confront 21st century challenges in food and drug safety. In the hearing today, I believe we should be careful as we react to the testimony to focus on what we need to understand. If we are serious about making progress on resources, we will need strong bipartisan support. Such support was behind the budget increases for the Centers for Disease Control and the National Institutes of Health. We should resist taking shots at the Administration or the Commissioner. The FDA's problems are longstanding and can be traced to both political parties.

It would be very tempting to pile on the negative findings so much that we create an image in the public's mind of an agency that cannot be fixed. That burning down the village to save it approach won't work. The more we do that, the harder it will be to make a case down the road that more resources here and more scientists there can actually fix the problem. Our job will be to build evidence for areas where we can make a bipartisan case and we should focus on that objective.

There are a few areas I am hopeful we can examine today. First, I understand the Science Board report provided an outline for a strategy to restore FDA capabilities in a number of areas. I would like a clear understanding of some of those structural fixes that had been proposed and how these will contribute to the agency's mission, and where possible, I would like to know what would be the absolute top priorities. I would like to understand how the board's strategy dovetails with the Commissioner's own strategy for focusing the agency on current and future risk. How will the two work together and what measures or indicators can we expect that will help us see how important gaps can be filled?

Second, we have to be wary of the bureaucratic imperative to expand into areas beyond the agency's basic mission. Bureaucracies such as the FDA tend to want to expand their turf through more regulation and litigation. Thus, some additional resources wind up diverted for expanding turf, not enhancing basic mission capacity. We have to be very candid about the fact that many problems that this subcommittee has identified raise questions about management of resources and decisionmaking at the agency.

As we consider the Science Board's recommendations, we have to reconcile those with our own work. We have to explore how we can develop confidence that money expended will be expended efficiently on the most pressing and essential needs. I would like to hear from the GAO about improving the management culture at the FDA.

The subcommittee needs to complete its own diagnosis of the FDA's problems. For example, we know Congress responds to the FDA's needs when the case can be made. After September 11, the Secretary of HHS, Tommy Thompson, made his case to Congress and the Administration for more resources, some 600 FDA inspec-

tors, and we responded. We know now that those inspectors have fallen off the books. How did this happen and why did it happen?

Finally, we should also recognize that we have a great opportunity to focus both on the management and structural reforms as well as resources needed. We are fortunate to have Commissioner von Eschenbach here today. He has demonstrated by this report, other actions and even his presence today that he is seeking a way to move this agency into the 21st century. We should support him in this effort, and the challenge today will be to work with each of the panelists to start building the bipartisan case we need to move forward, and I guess in ending, in one year the Commissioner has been here four times and in three of those testimonies he sat through the hearing prior to his testifying. He will do so today. He is in the audience. We appreciate that. That doesn't include the individual staff meetings like yesterday that you have committed to. I do think that does represent goodwill and hopefully we can work together to move forward.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Shimkus.

Mr. Inslee for an opening statement, sir.

OPENING STATEMENT OF HON. JAY INSLEE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mr. INSLEE. Thank you. I want to thank Mr. Stupak for having these hearings, and I want to focus on the problem of medical scams, and this is a problem one would have thought that we had under control in this country after centuries of flimflam artists using people's desperation to their profit. But I was looking at a Seattle Times series about the explosion of the medical scam industry in the United States and it does appear to be not just an aberration but a multinational industry that we are totally not controlling in the United States, and I was flabbergasted to read the stories of what is going on out there using fancy flashing light electronic gizmos to make people think they are being cured and in fact they are being abused by these medical scam artists and it is not a small thing.

Just to tell you how tragic it can be, I will just tell the story of one lady named Joan Burgraff, a 58-year-old woman in Tulsa who was having pain and had lost her husband to cancer. She was upset with the medical community, or at least didn't think the medical community could help her. She started to develop pain in her joints so she went to a clinic by a person who had been trained in Seattle using a device called the EPFX and they took this woman in and they strapped her to a chair and put all kinds of official looking electronics on her and plugged into a little box with a bunch of flashing lights and allegedly diagnosed her condition, and the operator later said that the way it worked is, you put the machine in zap mode and they zapped her for some period of time, telling her that they were taking care of her problem. Months and months went by. Finally she became worse and worse, developed terrible, terrible situations, blacking out, tremendous pain. Her son finally convinced her to go to a hospital. They had to transfer her by helicopter to get her to the hospital at that point. And as the story, as you can tell, ended, she had undiagnosed leukemia and

died shortly thereafter. Now, we don't know what her course would have been but we do know that it was inhuman to expose this woman to some multi-colored light device that robbed her of any real hope that she really may have had, and I really can't think of a viler thing to do than to use people's desperation, which is going on over and over again in this country. That is the story in Tulsa.

A story closer to home, a woman named Karen MacBeth, who is 59, had cancer, terrible pain, looking for some alternative, went to a "clinic" in Port Orchard, Washington, using a machine called the EPFX machine. Same thing happened to her. She spent $17,000 out of her life savings. She was told that the treatment could cure cancer. She believed that. Later on the machine turned out to be something that would basically generate random electronic flashing pulses but no relationship to anybody's health, and she later died, having had no effective medical treatment that was delayed because of this scam.

Now, I will point out that from this excellent work by the Seattle Times, we find out this is something that is going on all over the country. There is one company with a fellow American who is now avoiding an indictment who is in Budapest that is operating these scams in 22 different countries around the world. This is like a major international corporation, and the fact that the United States of America can't shut it down is really sad. It is kind of pathetic, really, that we know that this is going on on a routine, consistent, repeated basis across this country and we can't shut these people down.

So we need to know how we address these mega scams' multinational efforts, how we really look at this honor system which is allowing people to get these machines in being treated as "biofeedback" machines and then they are told to the patient that they cure everything from cancer to osteoporosis to you name it, how we are going to get over this problem of using independent review boards, because some of these machines I have talked about, they have gone through a loophole using "independent review boards" to treat them as clinical trials while they are really just perpetuating these scams, and how finally we are going to get targeted resources and IT systems into the FDA so that they can finally find out what is even out in the marketplace, and I hope these hearings will be helpful to really get to the bottom of this. It is just incredible that this is going on in the United States and we have got to put a stop to it. Thank you.

Mr. STUPAK. I thank the gentleman for his time. You are talking about the EPFX machines and they are being used also in Michigan. You are correct in that there is a nine-count warrant against the so-called inventor of these machines for a scam, and the FDA did bring that charge against him. The gentleman has fled to Budapest, Hungary, and the committee is looking at it at your urging, an area we will take a look at. If we have a warrant for the individual that creates the machines, why do we still allow them in the country? It is still beyond me. It is something we will look at.

Mr. Barton for opening statement, please.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Mr. Chairman.

As most of us know, we are having a hearing in the Health Subcommittee right now about SCHIP, which I have been asking for for almost a year, so I am going to have to go up there some too so I am not being disrespectful to this hearing, but I will come back and shuttle back and forth.

Obviously today we are having an important hearing on the future of the FDA. We are going to take a look at the latest study about FDA and its science mission, mission at risk. It was prepared by the Science Advisory Board, Subcommittee on Science and Technology. I don't think it is a big news flash that the report found that the scientific capacity of the FDA is eroding as a result of lack of funding. We have got hearings in this committee as far back as 1955 that says the same thing. From the 1955 hearing, the quote was, "Adequate accomplishment on this recommendation will not be possible until much larger funds and facilities are made available to the FDA." That is over 50 years ago.

What is troubling about the latest report is the pessimistic tone almost across the entire report. There doesn't appear to be much positive anywhere, and obviously we can provide more funding. This committee has shown in a bipartisan fashion that we can do that. We just in the last Congress reauthorized and increased the authorization for the National Institutes of Health. It is one of my signature accomplishments as chairman. We are still trying to get the appropriators to follow through on what the authorizing committee has done but if there is a need and there is bipartisan will, we can get some of this stuff done. We shouldn't use this report to beat up on President Bush or Dr. von Eschenbach, who is out in the audience. Today is either the fourth or the fifth time that he has appeared in person before this subcommittee in the last year. I can't recall another FDA commissioner who has been that accessible in a personal way to the subcommittee and the full committee. We know that the problems at the FDA are longstanding. It is my opinion that they are not of a political nature. They are more of a process and just a structural nature. If we are going to get more resources for the FDA, we are going to have to work together and I am sure that Mr. Stupak and Mr. Dingell want to do that.

We also know that when the Congress does provide more funds to an agency like the FDA, sometimes the money just disappears. It just goes into bureaucracy and we never see it again. For example, 6 years ago after 9/11 and the anthrax attacks, Health and Human Services Secretary Tommy Thompson came before the committee and the Congress and asked for more than 600 new FDA inspectors at the border. We gave him the money, he got the inspectors. Five years later the inspectors are gone. What happened? As the FDA continues to struggle to meet its responsibilities in this 21st century, we need to make sure that their struggles are not simply a result of a bureaucracy that takes money and swallows it up and we never see it again.

I am very pleased that we are going to have a panel of experts before us today. I am sure that they are going to be frank and I

am sure that they are going to give us honest answers about what they think is really the problem. As I have said, I am also pleased that Commissioner von Eschenbach is here. He is going to have a long day today. The usual practice is for a presidential appointee to go first and then to clear out. Dr. von Eschenbach is going to sit here and listen to the experts so that when he appears before us this afternoon, he will have had the comfort of hearing what the folks before him had to say.

So Mr. Chairman, I am glad that we are having the hearing. I am going to be going back and forth but obviously we want an FDA that is up to snuff on the science mission so that it can do all of its missions also. Thank you.

Mr. STUPAK. Thank you, Mr. Barton. I would also note that there is a Telecommunications and Internet Subcommittee hearing also going on today so Mr. Dingell has three different hearings going at once. It keeps us all busy, and I know members will pay attention to their assignments but we will be shuffling back and forth all day.

With that, let me yield to Mr. Dingell, chairman of the full committee, for an opening statement, please, sir.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, thank you for the recognition. I want to begin by commending you for today's hearing and for your fine leadership of this very, very important subcommittee, and I want to say a word about my friend, Mr. Barton, and I want to express to him my appreciation of his leadership, cooperation and ability and the fact that he and I continue our ability to work together on matters affecting the public interest, and with that expression of respect and affection, I want him to know my appreciation for him and his service.

Mr. Chairman, I also want to commend our panel on which I will comment a little later. As you stated earlier, Mr. Chairman, the Food and Drug Administration is responsible for ensuring the safety of nearly $1 trillion of products used by Americans every day from medical devices to foods to pharmaceuticals and even pet foods and foods which are manufactured and products which are manufactured in this country and around the world. Each of us probably uses a product or many products each day that has been reviewed, studied or regulated by FDA, or perhaps not regulated by FDA as it should for want of resources and ability or personnel to carry out its responsibilities.

Yet today we will hear more bad news concerning the safety of these products. This morning the Congress and the American people will hear again from a panel of world-renown industry and academic experts who were directed by the Commissioner, Dr. von Eschenbach, to review the state of FDA. I believe this committee upon conclusion of its considerations will find that they aren't doing at FDA as well as they could or should. The report includes many troublesome findings about the FDA but mostly it concludes that the agency's mission is now at risk, an important conclusion, and it means that the health and safety of Americans are at risk

as well. The Congress, the Food and Drug Administration Commissioner and the Administration must now focus on these situations and find solutions quickly.

In December 2006, the Commissioner of FDA requested the Science Board to form a special subcommittee to assess whether science and technology at the agency is capable of supporting existing and future regulatory operations, and it is into this which we will be inquiring today. This subcommittee had extensive input from 30 external advisors representing industry, academia and other government agencies. These experts were chosen based on their extensive knowledge of cutting-edge research, budget, science and management operations. Their report is one of the most extensive reviews of FDA that I have seen and I believe we must pay close attention to what these experts found. I think that the Nation owes great gratitude to those who helped compile the report, particularly those who will testify today, and I express to them my personal appreciation and that of the committee. Each of them committed substantial personal time to complete this report. The report is straightforward with findings that are difficult to face or to deny. I will note that the practical effect upon each of them is that they had served 2 years without pay in carrying forward this important public responsibility.

Their testimonies along with the Government Accountability Office witnesses and the Congressional Research Service will describe FDA as an agency that is struggling to keep the Nation's food and drug supply safe and effective. Specifically, they are going to describe FDA's difficulties in inspecting foreign-manufactured drugs and medical devices that are sold in the United States, something which threatens to us a very real possibility of a significant calamity befalling our people, FDA's faltering ability to enforce its own regulations and to conduct rulemaking, FDA's substantially diminished capacity to inspect food production facilities, whether farms or processing plants, FDA's inadequate IT infrastructure that is antiquated, unstable and incapable of supporting key agency missions and finally, FDA's lack of human and technological resources and its effect on its scientific and regulatory responsibilities and capabilities. I would note that I have not found enough concern in this report about the number of personnel, the training and the adequacy of the personnel, the support facilities which they have or the budget of the agency which would enable to carry out its responsibility, and those are matters into which this committee will be going with rather more diligence.

Sadly, Mr. Chairman, most of these findings are not new to this committee. This subcommittee had more than five hearings alone last year documenting these persistent problems confronting FDA. Our constituents are growing weary of these events. They are losing confidence in the ability of the agency to protect them from products they use daily. And I would point out that this problem of the inadequacies of the agency is not new. I have had telephone calls with commissioners of FDA over the years in which they said oh, we are going to be leaner and meaner, oh, we are going to do more with less, and I have always had to observe that on the basis of my experience, they are capable only of doing much less with the

much less which they are being given, something about which we can properly express great dissatisfaction.

I want to commend the Commissioner for requesting this review and I look forward to his testimony about proposals to fix the agency. FDA, HHS and the Administration must address these failures and vigorously and work with the Congress to develop a real plan to strengthen FDA and to assure its ability to carry out the critical mission of FDA for the people of this Nation. But to assist the Congress in this and to work with us to achieve a proper solution to the problem, we are going to have to expect that FDA will be honest with themselves and that the FDA will be honest with us about budget, personnel, capabilities in terms of support facilities like the laboratories which they have been trying under Administration direction to close, and unless we have an honest appraisal of these matters, I have serious doubts that FDA is going to be able to be resurrected in any fashion that will satisfy either the agency or this committee.

I thank you, Mr. Chairman.

[The prepared statement of Mr. Dingell follows:]

STATEMENT OF HON. JOHN D. DINGELL

Mr. Chairman, I commend you for holding today's hearing. As you stated earlier, the Food and Drug Administration (FDA) is now responsible for ensuring the safety of nearly a trillion dollars of products used by Americans every day. From medical devices, to food, to pharmaceuticals, and even pet food, each of us probably uses a product everyday that has been reviewed, studied, or regulated by the FDA.

Yet today, we will hear more bad news concerning the safety of these products. This morning, Congress and the American people will hear for the first time from a panel of world-renowned industry and academic experts who were directed by Commissioner Von Eschenbach to review the state of FDA. Their report includes many troubling findings about FDA, but most importantly, it concludes that the agency's mission is now at risk, which means the health and safety of Americans are at risk, as well. The Congress, the Food and Drug Commissioner, and the Administration must focus on these findings and find solutions quickly.

In December 2006, the FDA Commissioner requested that his Science Board form a special subcommittee to assess whether ″science and technology″ at the agency is capable of supporting existing and future regulatory operations.

This subcommittee had extensive input from 30 external advisors representing industry, academia, and other government agencies. These experts were chosen based on their extensive knowledge of cutting-edge research, budget, science, and management operations. Their report is one of the most extensive reviews of FDA that I have seen, and we ought pay close attention to what these experts found.

Mr. Chairman, I think that the Nation owes gratitude to those who helped compile this report, and particularly to those who will testify today. Each of them committed substantial personal time to complete this report. The report is straightforward with findings that are difficult to face.

Their testimony, along with witnesses for the Government Accountability Office and Congressional Research Service, will describe an FDA that is struggling to keep the Nation's food and drug supply safe and effective. Specifically, they will describe:

- FDA's difficulties in inspecting the foreign manufacture of drugs and medical devices that are sold in the United States;
- FDA's faltering ability to enforce its own regulations and conduct rulemaking;
- FDA's substantially diminished capacity to inspect food production facilities, whether farms or processing plants;
- FDA's inadequate IT infrastructure that is antiquated, unstable, and incapable of supporting key agency missions; and finally
- FDA's lack of human and technological resources and its effect on its scientific capabilities.

Sadly, Mr. Chairman, many of these findings are not new to this Committee. This Subcommittee had more than five hearings alone last year documenting these persistent problems confronting FDA.

Our constituents are growing weary of these events. They are losing confidence in this agency's ability to protect them from the products they use daily.

I commend the Commissioner for requesting this review and I look forward to his testimony about his proposals to fix this agency. FDA, HHS, and the Administration must address these failures and work with the Congress to develop a real plan to strengthen FDA and ensure its ability to carry out its critical mission for the people of this Nation.

Mr. STUPAK. Thank you, Mr. Dingell.

Mr. Murphy for opening statement.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Mr. MURPHY. Thank you, Mr. Chairman, for holding this important hearing on the FDA, and I would like to thank the witnesses for attending and sharing their expertise with us. I am especially glad to have Dr. Garret FitzGerald from my home State of Pennsylvania present and I look forward to hearing from each of you.

We are here today to take a comprehensive look at the FDA, its mission, its resources, and from this we have to determine how to best ensure this agency has both the resources and the authority to do its job. Of course, this topic is not new to this subcommittee. We have spent considerable time examining these issues already. Last year we had four hearings on food safety and last November we closely examined the FDA's role in drug safety. Today our witnesses will respond to and comment on a report recently completed by the Science Board, and this report concludes the following: The FDA cannot fulfill its mission because its scientific base has eroded. It cannot ensure the safety of food supply because too few inspections and a lack of timely enforcement cripple our ability to respond to outbreaks. While food imports have increased over the past 35 years, the FDA has experienced a 78 percent reduction in food inspections, and its IT infrastructure is obsolete and unstable. I am most concerned that this report does little to ease my fear that the FDA does not do enough to protect our food and drug supply.

During a hearing this subcommittee held on November 1, 2007, I asked the witnesses if they would allow their children to take prescription drugs knowing they contained active ingredients imported from China. All the witnesses seemed to reluctantly answer but said yes, yet we know that China has over 700 firms importing drug products into this country and yet the FDA only conducted 15 inspections.

While I am concerned we must do more, I know we have the capacity to responsibly expand the FDA and help it. Recently we have been successful in expanding the NIH and the CDC. We need to take a similar approach to the FDA but also help make sure it has the tools to be efficient and remove bureaucratic barriers. The FDA is under pressure to be scientifically thorough, swift in their reviews and getting the needed drugs to market and absolute in their inspections. They are criticized for being too slow or too fast. It seems sometimes they are criticized for being too superficial or too obsessive. Where they are working to improve food and drug safety, we want them to be a source of excellence but where bu-

reaucracy stands in the way, we cannot understand why we can't get rid of that.

During my time in Congress, I remember hearing about the fact that there are about a dozen different agencies that administer as many as 35 laws that make up the Federal food safety program. No single agency oversees them all. This is a nonsensical and fragmented system which as far as I know still has this strange division wherein the Department of Agriculture inspects open-faced meat sandwiches and frozen pepperoni pizzas while the FDA inspects close-faced sandwiches and cheese pizzas. I think we can fix that problem, can't we?

I don't know what other kind of changes that we will hear from the FDA but I am looking forward to hearing any ideas that will improve the efficiency of this agency so it is not just a matter of putting more money into but it is a matter of giving the tools they need to become better and faster and more thorough.

I look forward to the testimony of today's witnesses, and I yield back.

Mr. STUPAK. I thank the gentleman.

Mr. Melancon, I understand you are going to waive your opening and therefore I go to Mr. Waxman for an opening statement, please.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. I don't know how much more evidence we need to realize that FDA is in a crisis. Our choice really is clear. Either we are going to make sure this agency has the ability with the resources necessary to do its job or we are going to watch it continue to deteriorate. We have had a number of outside reports. We are now going to hear about the Science Board report from within FDA itself. The Institute of Medicine and the Government Accountability Office both documented the chronic underfunding of the agency and we know what that has meant as we have seen illnesses and even deaths associated with unsafe foods, drugs and medical devices. This is concerning in and of itself but it has also made us acutely aware of the bare thread by which FDA now hangs and of just how close we are to a large-scale catastrophe.

The Science Board has done an outstanding job. They have highlighted the erosion of FDA's scientific capacity that has left it unable to fulfill the frightening number of critical regulatory and public health responsibilities. FDA, they say, lacks the staff, the IT infrastructure to conduct appropriate inspections of drugs and medical device manufacturers, to oversee the ever-increasing number of imported products entering the country and to protect against tainted and unsafe foods, just to name a few.

While, as the Science Board indicated, we know that there are dedicated and hardworking FDA staff to thank for the fact that we have avoided more catastrophes with our food, drugs and medical devices, we can't expect them to remain working under these grueling conditions for long. We need in order to fix this situation the best information from the Administration on how much funding

FDA needs to resume its position as the gold standard for the rest of the world, and I was disturbed that when the FDA asked its science committee to make recommendations, that is one area where they asked them not to make recommendations, not to spell out how much money they may need to fulfill their responsibility. I hope that is not an indication of what we are going to see when we get the President's fiscal year 2009 budget. The Science Board report very clearly lays out the problems with which the agency is grappling. It should be seized upon by this Administration to make its case for why FDA needs more resources. We absolutely must have accurate and specific numbers that reflect the urgency of the Science Board's findings.

I thank you, Chairman Stupak, for holding this critically important hearing. I hope the Science Board report will be the last report we have to read about the desperation at the Food and Drug Administration.

I want to yield back my time and tell you I am looking forward to the testimony of the witnesses. Unfortunately, there are two other hearings at the same time that I will also be trying to attend so I won't be here personally to hear every statement by the witnesses but I thank you for being here and I assume we will have a chance to review your testimony.

Mr. STUPAK. Thank you, Mr. Waxman.

Mr. Burgess for opening statement, please.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman, and I also am going to thank you for holding this hearing. It is a shame that there are so many hearings going on at the same time. This is an important subject but there are important subjects going on across the hall, which is why you see so many of us come in and out. Over the past year this subcommittee has undertaken a serious investigation regarding the safety of the Nation's food supply, and I thank the leaders of this committee on both sides of the dais for their leadership and their dedication to this important issue.

I would also like to thank the leadership of the FDA, Commissioner von Eschenbach, for his personal mission to increase safety in his own Federal agency. Although many problems have been apparent for decades, it was Commissioner von Eschenbach who in December of 2006 requested the detailed self-assessment from the Science Board. Specifically, the board was asked with the duty to assess whether the science and technology of the agency is capable of supporting the existing and future regulatory operations. It is a large task. Both the FDA Commissioner and the members of the Science Board subcommittee dutifully undertook this task and I thank everyone involved for working so hard on this vital mission.

The report we have before us today is very candid and reveals many things that we might not have wanted to admit. The first two major findings are extremely telling and frankly somewhat disturbing. Finding number 1: The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak, and specifically in the report it cites the staff and the information technology resources for its surveillance mis-

sion. Finding number 2: The Food and Drug Administration cannot fulfill its mission because its subcommittee workforce does not have sufficient capacity and capability, and again, they cite recruitment and retention challenges.

Considering that the FDA is responsible for almost 80 percent of the food we eat and regulates 25 cents out of every dollar spent in this country, these two findings should trouble not only everyone in the room but everyone in the United States. As we all know, our committee is responsible for passing legislation that helps to solve all sorts of ailments in the society: problems with food, prescription drugs, imported products, just to name a few. However, as I learned in my practice in medicine for 25 years, the only way to truly fix a patient's ailments is to make certain that the entire system was healthy. If a patient presents with an acute febrile illness because of bacterial pneumonia, he might be transiently helped with an aspirin but if you don't treat the underlying infection, you are not really doing the patient any good.

Commissioner von Eschenbach and the Science Board subcommittee are to be commended for their actions of trying to make the entire system healthy but also we understand there is some disagreement and confusion as to whether or not this report is final. After reviewing the findings, it seems hard to believe that this report can be anything but final, and I hope some of these questions are resolved today as regards to the finality of the report.

We all know the issue of increased resources will be a common theme today. We heard Ranking Member Barton address just his fact but he also referenced the work that was done by this committee on the National Institutes of Health reauthorization and we authorized a 5 percent increase in funding for the National Institutes of Health for the next 5 years. We were criticized because that wasn't a large enough investment in science and research in this country, and yet when a different party was in power this last summer and we had the opportunity to appropriate money for the National Institutes of Health, what did we do? We bumped it up 2 percent, not the 5 percent that was authorized. So clearly there is a disconnect between what happens at the level of this committee where we set the funding levels and at the level of the Appropriations Committee, and Mr. Chairman, I hope we are dutifully observant when we go through the budgetary and appropriations process that is just before us in the next few months to ensure that what we decide as far as the FDA's authorized budget limit is in fact met and funded when the appropriators meet later on in the year.

There is no doubt in my mind that an increase in resources is needed at the Food and Drug Administration but the resources obviously have to be invested wisely. We all know putting a band-aid on a broken arm, although it is a therapeutic agent, is not going to result in the desired cure. Our efforts will again fall short and the American people are the ones who will pay the price.

Thank you, Mr. Chairman, and I will yield back.

Mr. STUPAK. Thank you, Mr. Burgess.

Mr. Green for an opening statement, please.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing today on the FDA's recent self-assessment. When the Food, Drug and Cosmetic Act was passed in 1938, the FDA was a small agency with a relatively manageable task of ensuring compliance in regulatory issues. Today, no new pharmaceutical products or medical technologies can be used without FDA approval. Also, over the years the role of FDA has been expanded to review the safety of human food, animal feed, additives, new human and animal drugs and human biological products. The role of FDA is vitally important to the economic health of the United States. It is estimated the agency regulated more than $1 trillion in consumer products. However, while the number of products the FDA regulates grows, the budget of the FDA has been under considerable constraints. Last year incidences of tainted consumer products including spinach, peanut butter and pet food called attention to the FDA and their failure to ensure the safety of these products. Subsequent hearings on these issues by this committee revealed many of the issues including the inability to ensure the food safety of products from China and other countries.

What deeply concerns me is, I represent the Port of Houston, which is the busiest port in the United States in terms of foreign tonnage, second busiest in the United States in terms of overall tonnage, and the tenth busiest in the world. Many of the products that are imported through the Port of Houston arrive from these countries whether it is China, Mexico, Latin America or anywhere in the world but an FDA inspection lab is not located anywhere near the port or not even in Texas. I have met with FDA inspectors at the Port of Houston but we need more resources to test and inspect these products.

This report outlines a number of scientific operational resource and technology concerns the FDA is currently facing. It gives us a clearer picture of the ability of the FDA to support its necessary regulatory functions. Unfortunately, the picture painted by this report is bleak. The time to act on the recommendations is now and I hope the FDA and this committee will seriously consider the recommendations in the report on the Subcommittee on Science and Technology and move quickly to act on them.

I want to thank our witnesses for appearing today, and also I thank you, Mr. Chairman, for continuing these hearings and hopefully more in the future. Thank you.

Mr. STUPAK. Thank you, Mr. Green.

Ms. Blackburn for an opening statement.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Ms. BLACKBURN. Thank you, Mr. Chairman. I thank you for the hearing and I want to welcome all of our witnesses that are here today, and I also want to be certain that the Commissioner knows that I appreciate the request for an analysis of the FDA Science Board to assess whether the science and technology at the agency can meet and support the current and future regulatory needs. The

report concludes much of what is already known about the current state of the FDA, and of course we have all talked about it this morning. The agency is extremely deficient in its ability to inspect and secure the Nation's food and drug imports and is not currently situated to meet its regulatory responsibilities.

Reports of a crisis at the FDA have been cited for years and yet the agency's mission continues to expand as it assume more and more responsibility over consumer safety issues and acts if deficiencies are really no problem, just kind of standard operating procedure, and today we will hear testimony from several witnesses on the massive burdens placed on the FDA with regards to regulating the Nation's food supply, pharmaceuticals and more, and I am concerned with the problems the agency faces in order to meet the current regulatory obligations while others are talking about wanting to pile on another monumental task that would be requiring the FDA to regulate tobacco. Regulating tobacco would not only divert attention and resources from the agency's core competencies and missions but also would force the FDA into what would be uncharted waters.

This Congress should focus on improving the FDA's current regulatory system before it heaps additional responsibility on the agency. With the agency's documented weaknesses, logistical challenges and sporadic review capabilities, I am hopeful that today's witnesses can help this committee understand how it can best assist the FDA in reducing the incidences of such problems. The FDA, in my opinion, has yet been able to articulate a systematic processes best practices used to achieve and carry out their mission. That I would offer is a very serious problem.

While concern exists that the FDA does not receive adequate resources to fulfill its regulatory duties, I am wary of increasing FDA funding without increased accountability for how that money is going to be spent. I believe Congress should invest wisely in the agency. Then we should closely monitor the agency to be certain that they are aggressively seeking to carry out their mission, that they are working on timelines, that they have benchmarks, that they understand the process of best practices and that they understand that a continuing appropriation does not allow them to continue to be ineffective and inefficient. They are required to carry out their mission. They owe it to the taxpayers. It is not their money that they are spending. It is the taxpayers' money that they are spending and the taxpayers have grown very, very ill and fatigued with the lack of responsiveness from this agency.

Again, I want to welcome our witnesses. I am looking forward to hearing how we should move forward in making consumer safety priority number one with the FDA. It has the potential to save millions but also the opportunity to expose many people to risk and harm. It is a challenge. It should be a balancing act of priorities. It is going to require your best efforts, and I look forward, Mr. Chairman, to the balance of the hearing.

Mr. STUPAK. I thank the gentlewoman.

Ms. DeGette for an opening statement.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you, Mr. Chairman. I was going to waive my opening statement but then I looked at these startling statistics that I think we need to really think about as we talk about what the FDA is and should be doing. As you know, I have been working a lot on food safety over the last year or two and it is really shocking how at the same time we are bringing more and more food into this country from foreign countries, our inspection is less and less of this food.

For example, during 1990 to 2005, imports of FDA-related food increased from 2 to 15 million lines a year, which was a 650 percent increase, but at the same time Congress gave only a 13 percent increase in field personnel to the FDA. So here is what happened with food inspections. In 1973, the FDA inspected 34,919 food establishments. In 2006, when you have a burgeoning amount of our food coming from foreign countries, they inspected 7,783 establishments, a 78 percent reduction in food inspections at a time when we are showing that the food industry is rapidly expanding and going overseas.

So if anybody thinks that we don't need, number 1, a new way of thinking at the FDA, which the Bush Administration agrees with, but number 2, a vast amount of increased resources to make these things happen, then they are fooling themselves and we are only going to see an increasing number of newspaper and media accounts about the terrible problems that we are having with food, and unfortunately, this is going to go to the heart of what most of us consider our jobs to be as members of Congress, which is to protect the health, safety and well-being of our constituents.

And with that, Mr. Chairman, I yield back.

Mr. STUPAK. I thank the gentlewoman.

Mr. Walden for an opening statement, please.

Mr. WALDEN. Mr. Chairman, I am going to waive my opening statement so we can get on to the witnesses. Thank you, sir.

Mr. STUPAK. Very good. Thank you.

That concludes the opening statements by members of the subcommittee. On our first panel we have Dr. Gail Cassell, vice president, scientific affairs, and distinguished Lilly research scholar for infectious diseases at Eli Lilly and Company, Mr. Peter Barton Hutt, senior counsel at Covington and Burling, welcome. Dr. Catherine Woteki, global director of Scientific Affairs at Mars Incorporated, Dr. Garret FitzGerald, professor of medicine and professor and chair of pharmacology, Department of Pharmacology at the University of Pennsylvania School of Medicine, welcome, and Dr. Dale Nordenberg, managing director, Healthcare Industry Advisor at PriceWaterhouseCoopers. I thank all of you for being here and for your work.

It is the policy of this committee to take all testimony under oath. Please be advised that witnesses have the right under the rules of the House to be advised by counsel during your testimony. Do any of you wish to be represented by counsel during your testimony? Let the record reflect all witnesses indicated that they did not wish to be represented by counsel during their testimony.

So therefore I will ask you to please rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses replied in the affirmative. You are now under oath.

Dr. Cassell, we will start with you, please. Again, I thank each and every one of you for your work, especially on your scientific board report, and Dr. Cassell, as chair of that we would start with you, please.

STATEMENT OF GAIL H. CASSELL, PH.D., VICE PRESIDENT, SCIENTIFIC AFFAIRS AND DISTINGUISHED LILLY RESEARCH SCHOLAR FOR INFECTIOUS DISEASES, ELI LILLY AND COMPANY

Ms. CASSELL. Mr. Chairman, members of the subcommittee, as Mr. Stupak has said, I am Gail Cassell, vice president for scientific affairs at Eli Lilly and Company. I am a member of the Institute of Medicine of the National Academy of Sciences and am currently serving a second term on its governing board. Of relevance to my testimony today, I have previously been a member of the advisory committees of the directors of both the Centers for Disease Control and the National Institutes of Health. I also co-chair the congressionally mandated review of the NIH intramural program. I appear before you today as a member of the FDA Science Board, which you now know is advisory committee to the FDA Commissioner. I served as chair of the subcommittee that wrote the report of which you have already heard discussion this morning.

I want to point out that the report was unanimously endorsed by each of the 33 members of the subcommittee and also by the full Science Board that met and heard the findings of the report on December 3. On that day, the Science Board accepted the report as final. In other words, we understood and were told that the report in fact would be independent of those additional reviews that we recommended be done and undertaken by the Science Board. There is a letter to that effect here in the briefing book from Dr. Schein, who was then chair of the Science Board. The record of the proceedings of that meeting will show that due to the seriousness of the deficiencies found and the urgency of the situation, the Science Board was adamant that the report be broadly disseminated amongst the public and policymakers including it be published in the Federal Register so that the public would have full access to our findings.

I would like to point out a few things that we think make this report unique and the subcommittee unique. You have heard there were several other reports in the past. Our report is unique, first, in that it is only the second time in over a century that the agency has been reviewed by an external committee as a whole entity, and we can elaborate on why we think that is important in the discussion. Second, the committee was composed of leaders, not from a single sector but as you have heard this morning, leaders from industry, academy and other government agencies. The expertise and level of accomplishments of the members are almost unprecedented in a single committee of this type, especially considering their breadth and knowledge and regulatory science and understanding

of the mission of the agency. Just to point out that the subcommittee did include expertise ranging all the way from a Nobel laureate in pharmacology to 14 members of the National Academies of Sciences including two engineers and also included a former assistant Secretary of Health, a former chief counsel of the FDA, and the first Undersecretary of Food Safety to USDA. You will hear from the latter two this morning.

For over a year this group of experts worked for thousands of hours including nights, weekends and holidays. It was the norm, not the exception, that when we met even by phone call we would have as many as 30 members actively engaged in discussion for 2 hours plus. Let me assure you this level of engagement by so many very busy people with diverse expertise is rare in such a committee, let alone that there would be such rapid consensus about its findings. How then do we explain this rapid consensus and the commitment to this exercise? It became rapidly apparent, I would say actually at the end of our first meeting, that the FDA suffers, as you have heard already this morning, from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities. If we think there are problems today, wait until the future and the future is already here in terms of the challenges that the agency will face.

Importantly for this group to understand, these deficiencies we found are agency-wide. They are not limited to a single program. They are not limited to a single center. In fact, the body of the report reports on and emphasizes those issues that were found throughout the agency that are crosscutting. The individual appendices, on the other hand, are independent reviews by our committee of each of the centers and three of the different programs. Since every regulatory decision at FDA must be based upon the best scientific evidence available, we concluded because of the deficiencies we identified that American lives are at risk. The level of concern by all members of our subcommittee and the members of the Science Board was and remains high, and thus the intensity of our commitment to this review and our insistence that the findings be broadly communicated and that immediate action be taken by the agency to address these deficiencies. The Science Board report discussed dozens of specific findings and concerns about FDA's ability to protect Americans. However, we will only emphasize seven of the principal findings in today's hearing.

First, there is no more quintessential governmental responsibility than the protection of basic commodities of American life such as our foods and drugs. Our subcommittee concluded that FDA is at risk of failing to carry out this mandate and as such are beginning to turn to unregulated products for solutions, as you have heard this morning. Throughout most of its 100-year existence, FDA has been recognized as one of the Federal Government's most trusted entities but this most valuable of agencies is deteriorating for lack of resources to fulfill its mission.

You will hear from Peter Barton Hutt that the demands upon the FDA have soared in recent years, as you will hear also from the Congressional Research Service and others. But not only have FDA resources not kept pace with its responsibilities, the agency's core programs have lost 1,000 people over the past decade. You will

hear this morning from Dr. Cathy Woteki, the first Undersecretary of Agriculture and a former dean of a veterinary school and now with the food industry, that the FDA cannot ensure the safety of our food supply. You will hear from Dr. Dale Nordenberg, formally of the Centers for Disease Control and head of information technology for the Center for Infectious Diseases there that FDA's information technology systems are woefully outdated and inadequate, posing a concrete threat to the agency's public health mission. You will hear from Dr. Garret FitzGerald from the University of Pennsylvania that innovations and advancements in science are outstripping FDA's capacity to regulate them, threatening not only the safe introduction of new technologies but also American leadership in pharmaceuticals, vaccines, biotechnology, medical devices, and by the way, food, and in fact we would argue that if this deficiency is not corrected, we will not realize the benefit from the large investment that this country has made and rightly so in biomedical research in this country. The patients will not in fact receive those new therapies in a timely manner and they will not get the review that they should based on the new science and advances in science if we don't correct what Dr. FitzGerald will describe to you this morning, and at a time in which U.S. competitiveness in science and medicine are under increasing challenges from overseas, a weak FDA will be a break on the very technologies that the United States is relying on for its medical and technological future, even from an economic standpoint.

And lastly then, I would just say that in conclusion, our report's findings echo, as you have heard this morning, study after study by the Institute of Medicine of the National Academy of Sciences, congressional committees, the Government Accountability Office and other expert bodies that have documented FDA's shortfalls and the resulting public health threat. We have been told that our report is the most comprehensive review done of FDA but not only an external group with access to the agency but it contains the most comprehensive analysis simultaneously by the agency itself and the capacity, their capacity and relationship to their regulatory authority. The last two appendices of the report are actually a self-assessment of FDA staff, the leaders of FDA, if you will. We asked them to identify what are the major scientific gaps not only in terms of technology but expertise in terms of allowing you to do your job and then by the way tell us how that links directly back to the regulatory mission. To my knowledge, this is the first time in history where you would have had this happen simultaneously and parallel but independently both by an external group of experts but also by your internal leaders. It is rare indeed.

Together we think these do represent a blueprint as well as the report on drug safety by the Institute of Medicine and some of the reports that you will hear today from GAO and others. We believe this gives a blueprint for moving forward to correct these serious deficiencies. Thus, it is now time, we would argue, for the reviews to stop and to take the necessary action to correct the deficiencies. We don't need to wait on more reviews. We need to begin to correct these urgent deficiencies that we have noted.

First and foremost, our subcommittee believes very strongly that there must be a strong commitment on the part of the FDA to un-

dergo the structural changes recommended in this and previous reports to strengthen the scientific base of the agency and to recruit and retain the most outstanding leaders in regulatory science. The American public and Congress deserve no less. The Congress and the Administration need to provide the resources necessary to bring the agency into the 21st century. That is not to say that we also don't need increased accountability, as Mrs. Blackburn has also pointed out.

We recognize that adequate resources, human and financial, will not be sufficient to repair the deteriorating state of science at FDA, which is why our committee also recommended significant restructuring, as I have already alluded to, but without a substantial increase in resources, the agency will be unable to meet either the mandates of Congress or the expectations of the American public regardless of management or leadership changes.

On behalf of our subcommittee, we thank Chairman Stupak and Chairman Dingell and Ranking Members Barton and Shimkus for holding this hearing and for your recognition of the seriousness of the deficiencies that we have identified and the urgency with which they need to be addressed. I must say on a personal note, I am very encouraged to have heard the statements given this morning by you, Mr. Stupak, and members of your committee and others that in fact you too recognize the seriousness of the deficiencies that have been noted.

In summary, however, I want to emphasize, please be assured that our findings and recommendations were made in the spirit of deep respect for the FDA, for its dedicated service to the public health provided 24/7. The urgency of our advisory is simply predicated upon the fact that we see signs of an increasingly chaotic environment descending upon FDA and the need to address the deficiencies that we have identified. Without immediate action, injuries and deaths from an overwhelmed regulatory system are certain and the costs to our society will be far greater than any dollar figure upon which we can arrive for rebuilding the agency. Currently I would point out that the each American pays about a penny and a half a day for the FDA. An increase to 3 cents a day would not in our view be a great price to pay for assurance that our food and drug supplies indeed are the best and the safest in the world. Thank you.

[The prepared statement of Ms. Cassell follows:]

STATEMENT OF GAIL H. CASSELL, PH.D.

Mr. Chairman and Members of the Subcommittee, I am Gail H. Cassell, Vice President for Scientific Affairs and a Distinguished Research Scholar for Infectious Diseases of Eli Lilly and Company and Professor. I am also Professor and Chairman Emeritus of the Department of Microbiology of the University of Alabama Schools of Medicine and Dentistry. I am a member of the Institute of Medicine of the National Academy of Sciences and am currently serving a second term on the governing board of the IOM. Of relevance to my testimony today, I have previously been a member of the Advisory Committees of the Directors of both the Centers for Disease Control and the National Institutes of Health. I also co-chaired the congressionally mandated review of the NIH intramural program. I appear before you today as a member of the FDA Science Board, Advisory Committee to the FDA Commissioner. I served as Chair of the Subcommittee on Science and Technology of the Science Board, which authored the report ″FDA Science and Mission at Risk″.

In December 2006, the Commissioner charged the Science Board with establishing a subcommittee to assess whether FDA's current science and technology can support the agency's statutory mandate to protect the nation's food and drug supply. The subcommittee was comprised of three Science Board members and 30 other experts. The subcommittee formally presented its report to the Science Board and FDA on December 3.

The report was unanimously endorsed by each of the 33 members of the Subcommittee and the full Science Board. On December 3, the Science Board accepted the report as final and dissolved the subcommittee. The record of the proceedings of that meeting will show that due to the seriousness of the deficiencies found and the urgency of the situation, the Science Board was adamant that the report be broadly disseminated among the public and policy makers, including posting it in the Federal Register.

The subcommittee review was unique in many respects. First, it is only the second time in over a century that the agency has been reviewed by an external committee as a whole entity. Second, the committee was composed of leaders, not from a single sector, but from industry, academia, and other government agencies. The expertise and level of accomplishments of the members are almost unprecedented in a single committee, especially considering their breadth and knowledge in regulatory science and understanding of the mission of the agency.

The subcommittee included expertise ranging from a Nobel laureate in pharmacology, 14 members of the National Academy of sciences (including two engineers), a renowned economist and specialist in workforce issues, a leader in health care policy and technology assessment, a former CEO of a large pharmaceutical company, a former Assistant Secretary for Health and Human Services who also headed global regulatory affairs within a large company for over 20 years, a former Chief Counsel for the FDA, and the first under Secretary for Food Safety at the U.S. Department of Agriculture overseeing the Food Safety and Inspection Service and coordinating U.S. government food safety policy.

For over a year, this group of experts worked intensively for thousands of hours, including many nights, week-ends, and holidays conducting their review. It was the norm, not the exception, that when we met, even by teleconference, we would have as many as 30 members actively engaged in discussion for over two hours. Let me assure you, this level of engagement by so many very busy people with diverse expertise is rare in such a committee let alone that there would be such rapid consensus about its findings. How then do you explain the consensus and commitment to this exercise?

It became rapidly apparent that the FDA suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities. It is agency wide, i.e. not limited to a single program or Center. Since every regulatory decision must be based upon the best available scientific evidence in order to protect the public's health, we concluded that American lives are at risk and that there is an urgent need to address the deficiencies. The level of concern by all members of the Subcommittee and the Science Board members was, and remains, high.and thus the intensity of their commitment to this review and their insistence that the findings be broadly communicated.

What we found is quite simply, demands of FDA have soared over the past two decades. Resources have not! Furthermore, we found that the Agency has not adapted in order to maximize existing resources by capitalizing upon the scientific resources in the academic community and other government agencies. The demands upon FDA have soared due to the extraordinary advance of scientific discoveries, the complexity of the new products and claims submitted to FDA for pre-market review and approval, the emergence of challenging safety problems, and the globalization of the industries that FDA regulates. The result is that the scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the food, drug, cosmetic and device regulatory system, and hence the safety of the public.

Briefly the Subcommittee found that:

- The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak.
- There is a fire-fighting regulatory posture instead of pursuing a culture of proactive regulatory science, especially related to food safety. Consequently, The nation's food supply is at risk.
- FDA cannot adequately monitor development of new medical products and adequately evaluate the safety of existing products because it is unable to keep up with scientific advances (genomics and related areas of science, wireless healthcare devices, nanotechnology, medical imaging, robotics, cell- and tissue-based products, regenerative medicine, and combination products).

- The FDA cannot fulfill its mission because its scientific workforce does not have sufficient capacity or capability.
- The FDA cannot fulfill its mission because its information technology infrastructure is sorely inadequate. It is problematic at best-and at worst it is dangerous.

Although our Subcommittee was asked to review gaps in scientific expertise and technology and not to assess available resources, it rapidly became apparent that the gaps were so intertwined with two decades of inadequate funding that it was impossible to assess gaps without also assessing resources. Our Subcommittee, therefore, spent considerable effort garnering as much information as possible about the current roles and responsibilities of Agency staff, available resources, the current status of science within the Agency, and the implication of emerging science for the future of FDA and the public's health.

Specifically, we found that FDA's shortfalls have resulted in a plethora of inadequacies that threaten our society-including, but not limited to:

- inadequate inspections of manufacturers
- a dearth of scientists who understand emerging new technologies,
- inability to speed the development of new therapies,
- an import system that is badly broken,
- a food supply that grows riskier each year, and
- an information technology infrastructure that was identified as a source of risk in every Center and program reviewed by the Subcommittee.

We concluded that FDA can no longer fulfill its mission without substantial and sustained additional appropriations. The current situation has developed over many years, the question is not why or how we got here but rather how do we strengthen FDA going forward? Our subcommittee strongly believes our report provides the required blueprint.

The report is unique in yet another important way. It not only provides an assessment by a rigorous review of the Agency by a diverse team of experts from the public and private sectors, but it also includes a simultaneous assessment by leaders of the FDA (as contained in Appendices L-M). Our Subcommittee requested staff to not only identify science and technology gaps but to link each directly to their specific regulatory mission. This comprehensive external/internal analysis--done at the same point in time for an entire Agency--is indeed rare.

We recognize that adequate resources-human and financial-alone will not be sufficient to repair the deteriorating state of science at FDA, which is why our committee also recommended significant restructuring. But without a substantial increase in resources, the Agency will be unable to meet either the mandates of Congress or the expectations of the American public, regardless of management or leadership changes. Our findings are supported by many recent GAO reports as you will hear today as well as recent reports form the National Academy of Sciences.

It is now time for the reviews to stop and to take the necessary action to correct the deficiencies. First and foremost, there must be a strong commitment on the part of the FDA to undergo the structural changes recommended in this and previous reports to strengthen the scientific base of the agency and to recruit and retain the most outstanding leaders in Regulatory Science. The American public and Congress deserve no less. Then, Congress and the Administration need to provide the necessary resources to bring the Agency into the 21st Century.

On behalf of our Subcommittee, we thank Chairmen Stupak and Dingell and ranking members Barton and Shimkus for holding this hearing and for your recognition of the seriousness of the deficiencies we have identified and the urgency with which they need to be addressed.

Please be assured that our findings and recommendations were made in the spirit of deep respect for the FDA and for its dedicated service to public health provided 24/7. We fully recognize the extraordinary efforts of the committed FDA staff. It is apparent that they are the very reason further catastrophic food and drug events have been averted. The urgency of our advisory is simply predicated upon the fact that we see signs of an increasingly chaotic environment descending upon FDA, and the need to address the deficiencies we identified. Without immediate action, injuries and deaths from an overwhelmed regulatory system are certain, and the costs to our society will be far greater than any dollar figure upon which we can arrive at. I have attached a synopsis of our Subcommittee report to my statement and request that it be included in the recording of this hearing. Other members of the Subcommittee here with me today will summarize the most important findings and those in need of the most urgent attention.

FDA SCIENCE AND MISSION AT RISK

SYNOPSIS OF A REPORT OF THE FOOD AND DRUG ADMINISTRATION'S SCIENCE BOARD

DECEMBER 2007

INTRODUCTION

The Food and Drug Administration's (FDA) Science Board is an advisory committee to the Commissioner of FDA, chartered to assist the agency on a range of scientific matters, one of which is how the agency's scientific capabilities can be maintained so as to ensure that the agency can carry out its increasingly complex responsibilities. In December 2006, Commissioner of Food and Drugs Andrew VonEschenbach charged the Science Board with establishing a subcommittee to assess whether FDA's current science and technology can support the agency's statutory mandate to protect the nation's food and drug supply. The subcommittee was comprised of three Science Board members, complemented by 30 other experts from industry, academia, and other government agencies. Upon its completion after a year of intensive examination of FDA's programs and organization, the subcommittee's report was unanimously endorsed by all 33 members of the Subcommittee and the full Science Board. As the report's title suggests, the Board has concluded that FDA is an agency at risk of failing to carry out its mandate, and thus the nation and its citizens are at risk of grievous harm if the FDA is not committed to greatly strengthening its scientific base and if it is not given the means to ensure the safety of our foods, drugs, medical devices and other consumer products for which FDA is responsible.

A SUCCESSFUL FDA IS ESSENTIAL TO A SAFE SOCIETY

There is no more quintessential governmental responsibility than the protection of basic commodities of American life such as our foods and drugs. That fact was recognized over a century ago, when Congress created the Food and Drug Administration as one of the nation's first regulatory agencies. The Science Board report emphasizes that the need for an effective FDA is greater than ever before: FDA regulates 80% of the nation's food supply; plays a critical role in assuring the safety of therapeutic such as drugs, vaccines, and medical devices; regulates a vast number of other consumer products, ranging from television sets and cellular telephones to cosmetics, blood, and pet food; and has historically been the agency to which governments around the world look to make determinations about the safety of new products. Moreover, FDA is increasingly important to the nation's economic health, as it regulates a quarter of consumer expenditures, and the industries it regulates are innovative leaders in science and technology and among the few American industries with a positive trade balance with other nations. Further, FDA will be a critical component in combating emerging threats such as intentional contamination of the food supply and the threat of chemical, biological and radiological attack-as well as naturally occurring threats such as SARS, West Nile virus, Mad Cow disease and avian influenza.

FDA'S EXEMPLARY RECORD MUST BE MAINTAINED

Throughout most of its 100+ years existence, FDA has been recognized as one of the Federal government's most respected and trusted entities. The agency led the way in creating an effective, science-based ″safety net″ for consumer products. FDA's record of accomplishment is a long and distinguished one: new drugs are approved for marketing as fast or faster than anywhere else in the world; state-of-the art standards for safe food production have been established; a nascent medical device industry was helped to develop and grow into one of our most innovative; FDA decisions and procedures have been emulated by country after country around the world; products were labeled so as to give physicians and consumers reliable information about the products they prescribe and use; polls have consistently placed FDA at the top of any list of most trusted Federal agencies; and threat after threat was taken on and defeated, from unsafe pesticide use to improperly manufactured drugs to radiation emitted from a host of consumer products. FDA's scientists are widely considered among the most skilled and dedicated of our civil servants, and their commitment to excellence is unequaled.

A RECORD OF SUCCESS IS THREATENED

The FDA Science Board concluded that FDA's rich tradition of excellence has been slowly and steadily ″hollowed out″ by a failure of the Agency to strengthen its scientific organizational structure and by progression of budget cuts and inattention to the agency's needs. That deterioration, in turn, means that not only can the agency not fulfill its public health mission, but that the safety of our citizens and the well being of our economy are being undermined. Further, as the agency falls farther and farther behind, the public is increasingly losing confidence in the government's ability to protect them-already more and more citizens turn to unproven therapies that have not been subjected to FDA's rigorous scientific standards; and states are stepping in to regulate in FDA's absence, portending a balkanized, inefficient regulatory system without one national set of safety standards.

More specifically, the Board has identified a range of problems and program areas that need immediate attention, including the following:

- *The demands upon the FDA have soared due to the extraordinary advance of scientific discoveries, the complexity of the new products and claims submitted to FDA for approval, the emergence of heretofore unknown health threats, and the globalization of the industries that FDA regulates.* The metrics alone are daunting, for example, 125 new statutes added to FDA's workload by Congress in the past two decades, most without resources to implement them; 375,000 establishments making FDA-regulated products; a tripling in a decade of R&D in drugs and medical devices; an exponential increase in drug adverse reaction reports; and the emergence in recent years of extraordinary new health threats, such as SARS, E coli 0157H:7, AIDS, BSE, and many more. Perhaps most emblematic of this trend is the ten fold increase in the past decade of imports from other countries. Today, 15% of our food supply is imported from more than 100 nations, along with over half of our drugs, yet FDA has been given virtually no new authorities nor resources to address a dramatic change in the sourcing (and associated risk) from products made overseas, often in developing countries with little or no tradition of scientific rigor.
- *FDA's resources have not only not kept pace with its responsibilities, many critical agency programs have sustained actual cuts.* For example, FDA's food headquarters program has lost 20% of its scientists in just the past three years, despite an upswing in outbreaks of foodborne disease in the United States and a steady increase in contaminated seafood, produce and other foods being imported from foreign countries. Similarly, FDA has lost several hundred inspectors due to budget cuts since 2003, leaving the agency not only incapable of inspecting domestic manufacturers but also ensuring that most of the nation's ports have no FDA inspectors. Although one FDA function, new drug and device review, has received additional funding from industry-paid user fees, the agency as a whole as lost 1000 people over the past decade.
- *Innovations and advancements in science are outstripping FDA's capacity to understand and regulate them, threatening not only the safe introduction of new technologies but also American leadership in pharmaceuticals, vaccines, biotechnology, and medical devices.* The United States is on the cusp of another ″revolution″ in therapeutics that holds great promise for effective treatments of cancer, Alzheimer's, Parkinson's, and other previously incurable conditions. Breakthroughs in human genome research, molecular biology, nanotechnology, food processing technology, computational mathematics, in vivo imaging and many more are likely to change the face of medicine and food production, yet FDA has not been given the capacity to prepare for those breakthroughs. Tens of billions of dollars are being spent by both the public and private sector on the development of such products, yet FDA has been denied the relatively minor funding necessary to ensure their rapid and safe entry to market. At a time in which U.S. competitiveness in science, medicine, and food production are under increasing strain from overseas, a weak and under funded FDA will be a brake on the very technologies that the United States is relying upon for its medical and technological future. Furthermore, they have gaps in major areas of scientific expertise and they are no longer able to recruit the best and brightest in regulatory science nor to retain the ones them if recruited.
- *FDA cannot ensure the safety of our food supply.* It is difficult for leading scientists to reach such a dire conclusion, but the report's authors saw a food safety system in which basic inspection, enforcement, and rulemaking functions have been severely eroded, as has the agency's ability to respond rapidly to foodborne disease outbreaks and to keep pace with new regulatory science. FDA's food safety program is characterized as one steadily dropping in staffing, and in funding for essential functions such as development of its scientists and travel to scientific fora. The inspection rate of food processors can only be described as ″appalling,″ resulting from

budget cuts for food safety that has brought the agency from doing 35,000 domestic food inspections in 1973 to fewer than 8000 this year (meaning FDA inspects most facilities on average only every ten years). The foreign inspection rate is even worse, as the agency may manage to inspect a dozen foreign food manufacturers on 2008, despite the thousands of overseas producers sending food to our shores. The agency has no resources to conduct inspections of retail food establishments or of food-producing farms. Moreover, as FDA's leadership in food safety erodes, other countries are presenting themselves as the appropriate model for food safety standard setting, even though such standards can be unscientific and disguised trade barriers, to the detriment of principles of sound science and to market access for American food exports.

• *FDA's Information Technology systems are woefully outdated and inadequate, posing a concrete threat to the agency's public health mission.* The report's authors were extremely disturbed by the state of FDA's IT infrastructure. They found a situation problematic at best, at worst dangerous. Many of FDA's systems are far beyond their expected life span, and systems fail frequently (even email systems are unstable). Reports of product dangers are not rapidly compared and analyzed, inspectors' reports are still laboriously hand written, and the system for managing imported products cannot communicate with Customs and other government systems. These inadequacies do not only cause inefficiencies and waste, but more importantly mean that dangers lurking in information coming to the FDA are simply missed-such as drug adverse reactions that are duly reported but not flagged for attention due to incapacities in information management.

CONCLUSION

The findings and recommendations of the Science Board are not novel. Recent studies by the Institute of Medicine of the National Academy of Sciences, Congressional committees, the Government Accountability Office and other expert bodies have documented FDA's shortfalls and the resulting public health threat. It is now time for the examinations to stop and to take action. FDA's resource constraints cannot be reversed without a determined effort by Washington decision makers to rebuild this bulwark of our system of consumer protection. The report makes recommendations for significant restructuring of science at the FDA but it is also apparent that management nor leadership changes can be expected to have a significant impact, in the absence of very significant increases in resources. Without action, injuries and deaths from an overwhelmed regulatory system are certain, and the costs to our society will be far greater than any dollar figure upon which we can arrive at.

Mr. STUPAK. Thank you.

Mr. Hutt, opening statement, please, sir.

STATEMENT OF PETER BARTON HUTT, COVINGTON & BURLING LLP

Mr. HUTT. Mr. Chairman and members of the subcommittee, I am Peter Barton Hutt. I am a senior counsel at the Washington, D.C., law firm of Covington and Burling and a lecturer and food and drug law at Harvard Law School. During 1971 to 1975, I was privileged to serve as chief counsel for the Food and Drug Administration.

It is meaningless to discuss the scientific needs of FDA without first analyzing the resources, both money and personnel, currently available to the agency to accomplish its public health mission. I therefore have volunteered to prepare for our subcommittee a report that would document both the increasing responsibilities imposed upon FDA by Congress during the past 2 decades and the reduced appropriations provided by Congress for the agency during this period. Because of its central importance in demonstrating the need for additional congressional appropriations for FDA, I request that my report be included in full in the record of this proceeding.

Mr. STUPAK. Without objection, it will be.

Mr. HUTT. Thank you, sir.

Science at the Food and Drug Administration today is in a precarious position. In terms of both personnel and the money to support them, the agency is barely hanging on by its fingertips. FDA has become the paradigmatic example of the hollow government syndrome, an agency with expanded responsibilities, stagnant resources and the consequent inability to implement or enforce its statutory mandates. For the reasons set forth in my report, Congress must commit to a 2-year appropriations program to increase FDA employees by 50 percent and to double the FDA funding, and then at least to maintain a fully burdened yearly cost-of-living increase of 5.8 percent across all segments of the agency. Without these resources, the agency is powerless to improve its performance, will fall only further behind and, as Gail said, will be unable to meet either the mandates of Congress or the expectations of the American public.

My report first addresses the tremendous problems encountered by FDA in implementing the burgeoning number of new statutory responsibilities imposed by Congress each year. Table 1 of my report lists more than 100 statutes that directly impact FDA enacted by Congress only in the last 20 years since 1988. That is an average of more than six new statutes a year. In the history of our country, no other Federal regulatory agency has ever faced such an onslaught of new statutory mandates without appropriate funding and personnel to implement them. These unfunded mandates cascade down on FDA from all sides of the political spectrum. It is not a problem caused by bipartisan politics but the country cannot withhold the requisite scientific resources from FDA and then complain that the agency is incapable of meeting our expectations.

The lack of adequate scientific personnel and the resources to support them has had a major adverse impact on important FDA regulatory programs to assure the continued safety of marketed products. Ten specific examples are provided in pages 10 to 12 of my report.

Tables 4 and 5 of my report cover FDA appropriations for the 20-year period of 1988 to 2007. From 1994 to 2007, the agency's appropriated personnel decreased by 1,311 people and FDA's appropriated funding during this time increased by only about two-thirds the amount needed to keep up with inflation. It thus is obvious that FDA has become increasingly impossible to maintain its historic public health mission.

The deterioration of the FDA Field Force has been severe. The science functions within the FDA Center for Food Safety and Applied Nutrition which include, of course, dietary supplements and cosmetics, have been hit especially hard.

In conclusion, science is at the heart of everything that FDA does. Without a strong scientific foundation, the agency will flounder and ultimately it will fail. The scientific resources needed by FDA to carry out its statutory mission cannot be sustained on a minimal budget. Congress must commit to doubling the current FDA funding together with a 50 percent increase in authorized personnel over the next 2 years if this agency is to do its job.

Thank you, sir.

[The prepared statement of Mr. Barton Hutt follows:]

STATEMENT OF MR. HUTT

MAJOR POINTS

1.Science at FDA today is in a precarious position. In terms of both personnel and the money to support them, the agency is barely hanging on by its fingertips.

2.To correct this problem, Congress must commit to a two-year appropriations program to increase the FDA employees by 50 percent and to double the FDA funding, and then at least to maintain a fully burdened yearly cost-of-living increase of 5.8 percent across all segments of the agency.

3.During the past 20 years Congress has enacted more than 100 statutes that directly impact FDA, without providing money and personnel to implement them.

4.There are numerous unfinished FDA safety programs because of a lack of FDA resources.

5.During the past 20 years, faced with its ever-increasing responsibilities, FDA appropriations have resulted in a gain of only 817 employees and a loss of more than $300 million to inflation.

6.FDA regulation of food, dietary supplements, and cosmetics have been hit especially hard.

7.The deterioration of the FDA Field Force has been equally severe.

8.Science is at heart of everything that FDA does. Without a strong scientific foundation -- adequately funded by Congress -- the agency will flounder and ultimately fail.

TESTIMONY

Mr. Chairman and Members of the Subcommittee, I am Peter Barton Hutt. I am a Senior Counsel at the Washington, D.C. law firm of Covington & Burling LLP and a Lecturer on Food and Drug Law at Harvard Law School where I have taught a course on food and drug law for the past fifteen years. During 1971-1975 I served as Chief Counsel for the Food and Drug Administration (FDA). I appear before you today in my capacity as a consultant to the Subcommittee of the FDA Science Board that prepared the recent report on ″FDA Science and Mission at Risk.″

It is meaningless to discuss the scientific needs of FDA without first analyzing the resources -- both money and personnel -- currently available to the agency to accomplish its public health mission. At the first meeting of the Subcommittee I therefore volunteered to prepare a report that would document both the increasing responsibilities imposed on FDA by Congress during the past two decades and the reduced appropriations provided for the agency. My report is included in the Subcommittee's report as Appendix B and is attached to this testimony. Because of its central importance in demonstrating the need for additional congressional appropriations for FDA, I request that my report be included in full in the record of these hearings.

Introduction

Science at the Food and Drug Administration (FDA) today is in a precarious position. In terms of both personnel and the money to support them, the agency is barely hanging on by its fingertips. The accumulating unfunded statutory responsibilities imposed on FDA, the extraordinary advance of scientific discoveries, the complexity of the new products and claims submitted to FDA for premarket review and approval, the emergence of challenging safety problems, and the globalization of the industries that FDA regulates -- coupled with chronic underfunding by Congress -- have conspired to place demands upon the scientific base of the agency that far exceed its capacity to respond. FDA has become a paradigmatic example of the ″hollow government″ syndrome -- an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates. For the reasons set forth in my report, Congress must commit to a two-year appropriations program to increase the FDA employees by 50 percent and to double the FDA funding, and then at least to maintain a fully burdened yearly cost-of-living increase of 5.8 percent across all segments of the agency. Without these resources the agency is powerless to improve its performance, will fall only further behind, and will be unable to meet either the mandates of Congress or the expectations of the American public.

Congress and the nation therefore have a choice. We can limp along with a badly crippled FDA and continue to take serious risks with the safety of our food and drug supply, or we can fix the agency and restore it to its former strength and stature. If Congress concludes to fix FDA, however, this cannot be done cheaply. It will be

necessary to appropriate substantial personnel and funds to reverse the damage done to FDA in the past two decades.

Accumulating Unfunded FDA Statutory Mandates

My report first addresses the tremendous problems encountered by FDA in implementing the burgeoning number of new statutory responsibilities imposed by Congress each year. Table 1 lists more than 100 statutes that directly impact FDA enacted by Congress only since 1988 -- an average of more than six each year. These are in addition to the core provisions of the Federal Food, Drug, and Cosmetic Act of 1938 itself and another 90-plus statutes directly involving FDA that were enacted during 1939-1987.

Each of these statutes requires some type of FDA action. Many require the development of implementing regulations, guidance, or other types of policy, and some require the establishment of entire new regulatory programs. Virtually all require some type of scientific knowledge or expertise for the agency adequately to address them. Yet none of these statutes is accompanied by an appropriation of new personnel and increased funding designed to allow adequate implementation. In the history of our country, no other Federal regulatory agency has ever faced such an onslaught of new statutory mandates without appropriate funding and personnel to implement them. Instead, the agency is expected to implement all of these new unfunded congressional mandates with resources that, in the corresponding time, represent at best a flat budget. Not surprisingly, many of the new congressional mandates languish for years or cannot be implemented at all.

In addition to the laws listed in Table 1, which directly require FDA to take action, Congress has enacted a number of statutes of general applicability that place a large administrative burden on FDA in conducting its daily work. Representative statutes of general applicability that require substantial FDA resources for compliance are listed in Table 2. For example, in order to promulgate a regulation, FDA must at a minimum include, in the preamble, not only full consideration of all the substantive issues raised by the regulation itself, but also a cost-benefit analysis, an environmental impact discussion, a federalism evaluation, a small business impact statement, a determination whether there is an unfunded mandate impact on state or local governments, and an analysis of paperwork obligations. The proposed and final regulations must be reviewed and approved by the Department of Health and Human Services (DHHS) and the White House Office of Management and Budget (OMB). However well-intentioned, these responsibilities place a major burden on FDA and require that scientific resources be diverted from other areas in order to assure compliance. This has led FDA to avoid rulemaking wherever possible and to substitute informal guidance or to take no action whatever on important regulatory matters.

The statutes of general applicability are not the only directives that have a strong impact on FDA. Every President in the past 40 years has issued one or more Executive Orders that impose additional obligations on FDA. A representative sample is set forth in Table 3. These Executive Orders have the same binding status as a statute and can have as great or greater impact.

The combined weight of these unfunded FDA statutes, statutes of general applicability, and Executive Orders is tremendous. Each includes additional responsibilities for the agency without commensurate appropriations for personnel and funds. The result is that, with relatively flat funding and a very large increase in what the country expects from the agency, FDA is falling further and further behind.

These unfunded mandates cascade down on FDA from all sides of the political spectrum. It is not a problem caused by partisan politics. Nor does my report question the justification for these mandates. Rather, it is the undeniable fact that these mandates are unfunded, and thus that FDA lacks the capacity to implement them, that is objectionable. The country cannot withhold the requisite scientific resources from FDA and then complain that the agency is incapable of meeting our expectations.

Unfinished FDA Safety Programs

The lack of adequate scientific personnel and the resources to support them has had a major adverse impact on important FDA regulatory programs to assure the continued safety of marketed products. For example, on several occasions FDA has established comprehensive reviews of products after they have been marketed, either at the direction of Congress or on its own initiative. Virtually all of these reviews remain unfinished for lack of agency resources. Ten specific examples are provided on pages 10-12 of my report.

Lack of Adequate FDA Appropriations

No one outside FDA has enough information about the agency to conduct a zero-based budget analysis for FDA. It is likely that FDA itself has numerous materials

that would bear upon such an analysis, but the agency states that it is not able to make those public.

My report therefore pursues a different approach. Attached are tables that present a partial statistical history of the congressional appropriations for FDA personnel and funds for the past 20 years, compiled from publicly-available sources. Tables 4 and 5 cover the 20-year period of 1988 - 2007. As the last column in Table 5 shows, from 1988 to 1994 FDA's appropriated personnel and funding kept even with its increasing responsibilities and exceeded inflation. The agency's appropriated personnel increased from 7,039 to 9,167 (a gain of 2,128 people) and its funding from $477.504 million to $875.968 million (a gain of $398.464 million). In 1994, however, FDA hit a brick wall. From 1994 to 2007 the agency's appropriated personnel decreased from 9,167 to 7,856 (a loss of 1,311 people), returning it almost to the same level that was appropriated 20 years earlier. FDA's appropriated funding during this time increased by $698.187 million, but this was only about two-thirds the funding needed to keep up with FDA's fully burdened cost-of-living increase of 5.8 percent, compounded yearly. Thus, over the entire 20 years FDA gained only 817 employees -- an increase of 12 percent -- and lost more than $300 million to inflation, while faced with implementing the new statutes listed in Table 1 and the agency's substantial other core responsibilities under the 1938 Act. Confronted with a burgeoning industry as documented in Table 6, it became increasingly impossible for FDA to maintain its historic public health mission.

My report contains numerous examples of the impact of this lack of personnel and funds on FDA programs, particularly dealing with food and regulatory enforcement. The science functions within the FDA Center for Food Safety and Applied Nutrition (CFSAN) -- which include dietary supplements and cosmetics -- have been hit especially hard. In the 15 years from 1992 to 2007, CFSAN suffered a reduction in force of 138 people, or 15 percent of its staff. During the same period, Table 1 shows that Congress enacted several important new laws creating major new responsibilities for CFSAN, all of which required substantial scientific expertise for implementation.

The deterioration of the FDA Field Force -- which must daily make scientific evaluations of FDA-regulated products -- has been equally severe. Between 1973 and 2006 there was a 78 percent reduction in food inspections. FDA conducted twice the number of foreign and domestic food establishment inspections in 1973 (34,919) then in did for all FDA-regulated products in 2006 (17,641). The inability of FDA adequately to police the importation of food and drugs into the United States has been well documented by Congress during the past two years.

Conclusion

We must all recognize that FDA can increase its attention to high priority issues, or take on entirely new responsibilities, only in the following two ways. First, FDA can divert personnel from other priorities, thus leaving those other areas neglected. This is what happened with contaminated pet food, one of the many areas which have been neglected because of a lack of agency resources. Second, Congress can determine to provide adequate funding for all of the responsibilities that the country expects FDA to implement. But it is clear that, unless Congress adopts this second approach, FDA will of necessity be forced to follow the first.

Science is at the heart of everything that FDA does. Without a strong scientific foundation, the agency will founder and ultimately fail. The scientific resources needed by FDA to carry out its statutory mission cannot be sustained on a minimal budget. Congress must commit to doubling the current FDA funds, together with a 50 percent increase in authorized personnel, within the next two years. From then on, it is essential that the FDA budget at least keep up with inflation and perhaps even more. Another report should be prepared in five years to offer advice on the state of science at FDA at that time and the resource needs that remain.

Mr. STUPAK. Thank you.

Dr. Woteki, it is time for your opening statement, please.

STATEMENT OF CATHERINE E. WOTEKI, PH.D., GLOBAL DIRECTOR OF SCIENTIFIC AFFAIRS, MARS, INC.

Dr. WOTEKI. Thank you, Mr. Chairman. I am Catherine Woteki. I am global director of scientific affairs for Mars, Incorporated, a global food and pet care business. Prior to joining Mars, I was Undersecretary for Food Safety in the U.S. Department of Agriculture and also dean of agriculture at Iowa State University.

I am pleased to have the opportunity to appear today to present the findings of the FDA Science Board's review of the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine. Between them, these two centers are responsible for assuring the safety of the Nation's food and feed supply, cosmetics, veterinary drugs and dietary supplements and for assuring that information on labels is truthful and not misleading. All together, this segment of the U.S. economy amounts to a staggering $466 billion in domestic and imported food sales, $18 billion in dietary supplements, $60 billion in cosmetics, $5 billion in veterinary drugs, $35 billion in animal feed sales and $15 billion in pet food sales.

Our committee's key finding is, and I am going to quote directly from the report, that "FDA does not have the capacity to ensure the safety of food for the nation. Crisis management in FDA's two food safety centers, the Center for Food Safety and Applied Nutrition," or CFSAN, as it is called, "and the Center for Veterinary Medicine," or CVM, "has drawn attention and resources away from FDA's ability to develop the science base and infrastructure needed to efficiently support innovation in the food industry, provide effective routine surveillance and conduct emergency outbreak investigation activities to protect the food supply." That is the end of our direct quote. The committee's recommendation as you have heard is to double FDA's appropriation over the next several years.

The crisis within FDA and particularly in these two food safety centers is the result of decades of neglect and erosion of CVM and CFSAN's resources needs. The current situation is not a reflection on the outstanding staff who do a commendable job under enormous pressure. They set priorities, they focus on the most important public health issues and they develop innovative ways to leverage what they have.

Rather, our review led us to conclude that CVM and CFSAN's basic functions of inspection, enforcement and rulemaking are severely eroded. Some examples you have already cited in your opening statements. Over 35 years, there has been a 78 percent reduction in inspections with food establishments, now inspected on the average once every 10 years. The recent pet food crisis strained an already overtaxed system. The Center for Veterinary Medicine received more than 18,000 telephone calls related to the melamine pet food contamination but they only have two full-time people who are devoted to working on pet food issues.

Since 2003, just in the last 5 years, CFSAN's workforce declined from 950 FTE to 771, and CFSAN no longer has the ability to generate the science needed to fulfill it human nutrition regulatory responsibilities.

Now, why has this happened? Well, a good part of that answer is the dramatic increase and diversification of the responsibilities assigned to these two centers. Since 2003, a half dozen new laws have been enacted that require significant investment of personnel and resources to implement. They include provisions that are related to food contact substances, the Bioterrorism Act, food allergen labeling, trans fat labeling, egg food safety, pandemic flu planning, and minor use and minor species health. These new responsibilities increase the complexity of the centers' tasks and increase the scientific demands that are placed on them but no additional funding

has been provided to enable the centers to implement these new responsibilities.

My written testimony provides more specific findings and recommendations and I request that that be inserted into the record, and I am happy to answer any questions that you may have.

[The prepared statement of Ms. Woteki follows:]

STATEMENT OF DR. WOTEKI, PH.D., R.D.

Mr. Chairman and members of the Committee, thank you for the opportunity to appear today to present the findings of the FDA Science Board's review of the Center for Veterinary Medicine and the Center for Food Safety and Applied Nutrition. Between them, these two centers are responsible for assuring the safety of the nation's food and feed supply, cosmetics, veterinary drugs, and dietary supplements and for assuring that information on labels is truthful and not misleading. All together, this segment of the US economy amounts annually to $466 billion in domestic and imported foods sales; $18 billion in dietary supplements, $60 billion in cosmetics, $5 billion in veterinary drugs, $35 billion in animal feed and $15 billion in pet food sales.

Our committee's key finding is that ″FDA does not have the capacity to ensure the safety of food for the nation. Crisis management in FDA's two food safety centers, Center for Food Safety and Applied Nutrition(CFSAN) and Center for Veterinary Medicine (CVM), has drawn attention and resources away from FDA's ability to develop the science base and infrastructure needed to efficiently support innovation in the food industry, provide effective routine surveillance, and conduct emergency outbreak investigation activities to protect the food supply″ (Report of the Subcommittee on Science and Technology, FDA Science and Mission at Risk, November, 2007, p. 3).

This crisis is the result of decades of neglect and erosion of CVM and CFSAN's resource needs. In contrast to drug discovery and development, FDA's food evaluation methods have not kept pace with evolving risks, and evolving science These centers are strapped for resources and can accomplish little beyond addressing the top priority of the moment. Major issues of public health concern are not being addressed such as cosmetic safety and the many regulatory responsibilities FDA has for human nutrition

The current situation is not a reflection on the outstanding staff who do a commendable job under enormous pressure. They set priorities, they focus on the most important public health issues, and they develop innovative ways to leverage what they have.

Rather, our review (which was conducted in winter and spring of 2007 against a backdrop of cascading product recalls) led us to conclude that CVM and CFSAN's basic functions of inspection, enforcement and rulemaking are severely eroded. Over 35 years, there has been a 78% reduction in inspections with food establishments now inspected, on average, once every 10 years.

The CVM workforce consists of 375 FTE, 4% of FDA total, but it faces unique challenges in the number and diversity of species it must address as well as maintaining a human health orientation. The pet food industry is a $15 billion a year business and largely falls under FDA's regulatory purview. The recent pet food crisis strained the already overtaxed system. CVM received more than 18,000 telephone calls concerning melamine pet food contamination. Estimates are that about 1 percent of the total volume of pet food was involved with a potential economic impact of $200 million. However, CVM is able to devote only two people working full time on pet food issues.

Since 2003, CFSAN's workforce declined from 950 FTE to 771 FTE. CFSAN no longer generates the science needed to fulfil its human nutrition regulatory responsibilities. The dietary supplement industry has grown to more than $20 billion in annual sales, and millions of Americans use those products every day. But the legislation authorizing FDA regulation of those products has never been funded, the practical effect being that the products and their health claims are essentially unregulated. The same can be said of the cosmetics industry, which has more than $60 billion in annual sales, but is overseen by an FDA staff of less than 20 people supported by $3.5 million budget.

Why has this happened? Most importantly, CVM and CFSAN have experienced a dramatic increase and diversification of their responsibilities. Since 2003, a half dozen new laws have been enacted that require significant investment of personnel and resources to implement. The new laws include FDAMA provisions related to

food contact substances, the Bioterrorism Act, FALCPA-food allergen labeling, trans fat labeling, egg safety food cGMP, pandemic flu planning, and minor use and minor species health. These new responsibilities increase the complexity of the Centers' tasks and increase scientific demands, but do not provide funding to enable the Centers to implement their new responsibilities.

Our finding is not a new one. In 1991, a previous committee reported to the Secretary of HHS its ″deep concerns about the viability of the foods program and the lack of Agency priority for food issues. Decline in resources and program initiatives during the past 10-15 years indicate a lack of Agency management attention and interest in this area, although public interest in, and concern for, an effective food program remain high″ (Report of the Advisory Committee on the Food and Drug Administration to the Secretary of HHS, May, 1991).

CENTER FOR VETERINARY MEDICINE - SPECIFIC FINDINGS AND RECOMMENDATIONS

CVM faces a spectrum of regulatory issues requiring high levels of science. These include methods to identify residues (synthetic and natural chemicals) and emerging infectious diseases; antimicrobial resistance monitoring (science and informatics base of NARMS); biotechnology (genetic engineering, cloning, use of phages, biopharma); and new technologies in drug manufacturing and delivery (nanotech, genetics, biomarkers, new approaches to characterizing microbial resistance). The key stressors that CVM faces are: the convergence of massive data volume and complexity with newly developed products from the ″omics revolution″; developing and maintaining unique databases with respect to species, endpoints, human health; and under staffing (375 FTE), vacancies in key scientific positions, and lack of funds (>80% of budget in salary). Our committee's recommendations are to: bolster CVM's in-house scientific capability in emerging areas relevant to veterinary medicine; improve IT capability, and integrate within FDA and with CVM partners (CDC, USDA), eliminate paper storage; and foster integration with cutting edge science activities across FDA and with external partners; and to expand the FDA Fellow Program.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION - SPECIFIC FINDINGS AND RECOMMENDATIONS

CFSAN's regulatory responsibilities require high levels in diverse sciences: food production sciences; risk mitigation at the source; consumer understanding of nutrition and food safety information; better labeling for public health; immunology; detection and prevention of foodborne viral diseases; safety of cosmetics; and adverse event reporting and analysis. The key stressors on the Center include: lack of resources (950 FTE in 2003 vs. 771 FTE in 2007; new mandates; elimination of research programs); globalization of the food supply; new food processing technologies; new threats to public health; ongoing response to emergencies; outmoded IT systems and laboratory instruments; and the fact that they are addressing only the highest priorities. Our committee's recommendations pertaining to CFSAN are to: add resources to attract, retain and leverage scientific expertise and regulatory research in priority areas; invest in 21st century regulatory science that could anticipate future food safety issues; and develop a cadre of professionals capable of applying the new science to emerging challenges; leverage research programs sponsored by NCTR, ARS, CSREES, CDC, NIH and DHS and conduct this activity with the Chief Scientific Officer; and not neglect cosmetics and nutrition.

Thank you, Mr. Chairman, I will be happy to answer questions.

Mr. STUPAK. Thank you, Doctor.

For the witnesses, any attachments to your testimony will be made part of the record, and again, we appreciate those. There are some good charts and statistics for us.

Dr. FitzGerald, please, opening statement, sir.

STATEMENT OF GARRET A. FITZGERALD, PROFESSOR OF MEDICINE AND PROFESSOR AND CHAIR OF PHARMACOLOGY, DEPARTMENT OF PHARMACOLOGY, UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE

Dr. FITZGERALD. Thank you, Chairman Stupak and members of the committee. My name is Garret FitzGerald. I am a professor of

medicine, chair of the Department of Pharmacology and director of the Institute of Translational Medicine and Therapeutics at the University of Pennsylvania. I have worked in the area of basic and clinical research relating to drug action for the past 30 years.

The FDA is charged with a mission fundamental to the safety of the Nation. Recent events—the cardiovascular hazards of COX–2 inhibitors, the uproar over the anti-diabetic drug Avandia, and the confusing and contradictory messages in the press about the lipid-lowering drug Vytorin have undermined our belief that the agency can safeguard the public and just as importantly communicate informed and unbiased information about drug safety.

The recent episodes of pet food and toothpaste contamination remind us that the bulk production of drugs, chemicals and cosmetics that reach the United States have largely moved offshore.

Serious as each of these incidents is, they are merely warning signs of a gathering storm. We ignore them at our peril. The FDA is the safeguard for the integrity of our drug supply and our food supply. Failure of the FDA to fulfill its mission would expose each and every one of us to danger, either from the willful intent of terrorists or the incompetence of manufacturers. Both the Institute of Medicine report and our subcommittee report, "FDA Science and Mission at Risk" have identified in plain terms a disturbingly systemic set of problems in the agency.

These include the politicization and instability of leadership, attrition of manpower, poor morale, structural and organization inadequacies, depleted infrastructure, and most importantly, critical gaps in scientific expertise and technology, as emphasized in this report.

These factors, many but not all reflecting a serious erosion of necessary resource, compound to undermine seriously the science base at the agency and its ability to fulfill its mandate.

How have we let the FDA get to this point? We have failed to maintain and upgrade the FDA over the past 50 years. Complex organizations, just like complex machines—and planes are good example—can continue to function effectively if preventively and reactively maintained. Last year a 57-year-old seaplane lost a wing and fell into the sea, killing 20 people on board. It had been poorly maintained, literally papering over the crack. However, the National Transportation Board assigned blame not just to the airline but also the Federal Aviation Agency (FAA) for not amending the rules with the times and having the appropriate regulatory requirements in place.

How can we move to restore the ability of the FDA to face the challenges of the world in 2008, not those of 1958? We must empower the FDA to cope with the rapidly changing science of drug development to ensure a pipeline of safe, innovative and effective medicines for our present and our future.

Firstly, we must reorganize the structure of science at the FDA. Unlike many agencies, this one must be grounded in science and science must permeate its activities and decisions. Amazingly, FDA presently lacks a chief scientific officer. We believe that such a position of leadership is necessary to guide the restructuring of the agency and provide constant advice to the Commissioner.

As Dr. Cassell has emphasized in her opening remarks, the FDA does not subscribe to rigorous peer review of their scientific programs and centers. To our knowledge, the Center for Drug Research and Evaluation and the Office of Regulatory Affairs have never been peer reviewed in their totality. Those centers that have been peer reviewed have been subject to this process so infrequently and not in a formal process.

Secondly, agency scientists need to become reengaged with the scientific community through attendance at meetings and encouragement to publish on regulatory science and through training.

Third, the presently segregated approaches to drug review and evaluation before and after approval for marketing must be integrated. Our information about how a drug works and how safely it works is fragmentary at the time of drug approval. We must exploit enhanced mega databases of clinical information, accessed in real time by agency scientists to assess drug safety post approval, and you will hear more from Dr. Nordenberg on this issue.

It took 7 years from the time we first predicted that Vioxx and Celebrex would cause heart attacks and stroke for the evidence to accumulate and this message to be delivered in unequivocal terms to consumers. This reflected a failure to integrate different types of scientific information and a reliance on a passive form of surveillance for safety signals once these drugs had reached the market. We must and we can do better.

Fourth, agency scientists may indeed be suspicious of safety signals but lack the freedom, the expertise and often the site where confirmatory tests must be pursued. We believe the FDA needs access to a neutral testing ground, a jet propulsion lab for the FDA.

So what is a JPL? When Boeing comes to the Department of Defense with a new engine for jet fighters, DOD doesn't say wonderful, let us write you a check. They may not have the facilities or the expertise to put it through its paces in Washington but they can turn to their collaborating experts in the JPL in Pasadena and subject it to rigorous assessment. The JPL provides a technologically advanced site for assessment. It provides independence and it provides expertise. This is the model we need for the FDA—academic sites where they can interact with experts in the emerging sciences to pursue evidence that is important to the regulators to clarify drug safety or efficacy, both before and after drug approval.

Presently, we approve drugs based on the ability to detect large average effects of benefit or risk in studies of large populations. This approval is clearly inadequate and essentially unchanged for the last 50 years. People vary strikingly in their response to most drugs, differences determined by the interaction of factors within their environment and their individual complement of genes. What matters most to most people is not whether there is an average affect in a population but how a drug will work with them.

The FDA is poorly placed to react, either to the challenges or the opportunities of this revolution in technology and medicine. Information from these new sciences is already providing an understanding of biological networks, which just as the interstate superhighway system lets us navigate the country will allow us to un-

derstand more comprehensively how our body works in health and how and where these highways are blocked in disease.

The FDA is not on this superhighway. It is stuck on a rural dirt track trying to get from place to place in a Model T. It needs a major infusion of resource to give it modern, fuel-efficient cars to get them on that superhighway. It also needs the drivers who can cope with the traffic and roads of the 21st century. We propose that it hires some drivers but gets up to speed by renting the rest part-time from the scientific fast lane, the academic sector.

It is unrealistic, short of the reintroduction of the military draft, to believe that the agency could ever recruit a sufficient number of individuals skilled in these emerging sciences to assess and interpret the information that will derive from them. The inability of FDA scientists rigorously to review these products will not only result in lost lives in some cases but in others will result in the failure of critical innovative life-saving medicines to reach the bedside, as you have heard from Dr. Cassell. For example, the only relevant expertise that the agency has in house in genomics, the most advanced of these new sciences, is fragmented, uncoordinated and paltry. Expertise in virtually every other aspect of the emerging sciences is essentially nonexistent in the FDA. Our subcommittee concluded that science in the FDA is indeed in a precarious because, as Dr. Cassell has emphasized, every regulatory decision that the agency makes is based on science and the deficit must be addressed.

It is realistic and desirable that the agency recruits or retrains a small cadre expert in these emerging sciences. However, their impact can be magnified if they are integrated into a larger network, a consortium of extramural scientists at academic sites—a jet propulsion lab for the FDA.

Besides amplifying the science base of the agency in the area of its greatest weakness, this JPL would provide a site in which the agency expands its capacity to assess medicines using the most modern technologies and a framework for educational exchange. This initiative should also revolutionize our approach to drug development, hastening the time to drug approval and detecting more efficiently and faster problems with drug safety. This initiative will empower the agency by harvesting the talent of the U.S. academic sector, the largest biomedical and bioengineering enterprise on the planet and one funded largely by the U.S. taxpayer.

In summary, we concluded that the FDA is in crisis. Its ability to fulfill its mandate has eroded to a critical degree and will rapidly deteriorate unless they are provided appropriate resources and the agency itself takes radical restructuring action. Both the Institute of Medicine and the Science Board reports identify steps that will enhance greatly the ability of the agency to guarantee the safety of the food we eat and the drugs and devices we are prescribed. This will require provision of a substantial increment in resources. However, best to do this while the levees are leaking rather than after the hurricane has hit.

[The prepared statement of Mr. FitzGerald follows:]

Testimony

of

Dr. Garret A. FitzGerald

before the

Subcommittee on Oversight and Investigations
of the
Committee on Energy and Commerce

House of Representatives

On

Science and Mission at Risk:
FDA's Self Assessment

January 29th 2008

Chairman Dingell and members of the committee,

My name is Garret FitzGerald. I am a Professor of Medicine, Chair of Pharmacology and Director of the Institute for Translational Medicine and Therapeutics at the University of Pennsylvania. I have worked on basic and clinical aspects of drug action for 30 years.

The FDA is charged with a mission fundamental to the safety of the nation. Recent events – the cardiovascular hazards of COX-2 inhibitors; the uproar over the antidiabetic drug, Avandia and the confusing and contradictory messages in the press about the safety

of the lipid lowering drug, Vytorin, have undermined our belief that the Agency can safeguard the public and communicate informed and unbiased information about drug safety.

The recent episodes of pet food and toothpaste contamination, remind us that bulk production of the drugs, chemicals and cosmetics that reach the US has largely moved offshore.

Serious as each of these incidents is, they are merely warning signs of a gathering storm. We ignore them at our peril. The FDA is the safeguard for integrity of our drug supply and our food supply. Failure of the FDA to fulfill its mission would expose each and every one of us to danger, either from the willful intent of terrorists or the incompetence of manufacturers.

Both the IOM report on "The Future of Drug Safety"[1] and our Subcomittee's report, "FDA Science and Mission at Risk"[2] have

identified in plain terms a disturbingly systemic set of problems in the Agency.

These include the politicization and instability of leadership, attrition of manpower, poor morale, structural and organizational inadequacies, depleted infrastructure and – most importantly- critical gaps in scientific expertise and technology as emphasized in our Science Board report.

These factors – many, but not all reflecting a serious erosion of necessary resource - compound to undermine seriously the science base of the Agency and its ability to fulfill its mandate.

How have we let the FDA reach this point?

We have failed to maintain and upgrade the FDA over the past 50 years. Complex organizations, just like complex machines –planes

are a good example – can continue to function effectively if preventively and reactively maintained.

Last year a 57 year old seaplane lost a wing and fell into the sea killing all 20 people aboard. It had been poorly maintained; literally, papering over the crack. However, the National Transportation Board assigned blame not just to the airline, but also to the Federal Aviation Agency – for not amending their rules with the times and having the appropriate regulatory requirements in place.[3]

How can we move to restore the ability of the Agency to face the challenges of the world in 2008, rather than those of 1958?

We must empower the FDA to cope with the rapidly changing science of drug development to ensure a pipeline of safe, innovative and effective medicines for our present and our future. As Dr. Cassell emphasized in her opening remarks, there have

been major scientific advances in drug discovery over the past decade, yet the way in which FDA reviews drugs and steers their development has not changed in over half a century.

Firstly, we must reorganize the structure of science at the FDA. Unlike many agencies, this one must be grounded in science and science must permeate its activities and decisions. Amazingly, FDA presently lacks a Chief Scientific Officer. We believe that such a position of leadership is necessary to guide the restructuring of the Agency and provide constant advice to the Commissioner.

As Dr. Cassell emphasized in her opening remarks, the FDA does not subscribe to rigorous peer review of their scientific programs and centers. Again, as she said, to our knowledge the Center for Drug Research and Evaluation and the Office of Regulatory Affairs have never been peer reviewed in their totality. Those

centers that have been peer reviewed have been so infrequently and not in a formal process.

Secondly, Agency scientists need to become re-engaged with the scientific community, through attendance at meetings and encouragement to publish on regulatory science and training.

Third, the presently segregated approaches to drug review and evaluation before and after approval for marketing must be integrated. Our information about how a drug works and how safely it works is fragmentary at the time of approval; we must exploit enhanced mega databases of clinical information, accessed in real time by Agency scientists to assess drug safety post approval. You will hear more about this in Dr. Nordenberg's testimony.

It took 7 years from when we first predicted that Vioxx and Celebrex would cause heart attacks for the evidence to accumulate

and this message to be delivered in unequivocal terms to consumers. This reflected a failure to integrate different types of scientific information and a reliance on passive surveillance for safety signals once these drugs reached the market. We must and we can do better.

Fourth, Agency scientists may indeed be suspicious of safety signals, but lack the freedom, the expertise and often the site where confirmatory tests might be pursued. We believe that the FDA needs access to a neutral testing ground –a "Jet Propulsion Lab".

What is a JPL? When Boeing comes to the Department of Defense with a new engine for jet fighters, DOD doesn't say, "wonderful, let's write you a check". They may not have the facilities or the expertise to put it through its paces in Washington, but they can turn to their collaborating experts at the JPL in Pasadena and subject it to rigorous assessment. The JPL provides a

technologically advanced site for assessment, independence and expertise.

This is the model we need for the FDA – academic sites where they might interact with experts in these emerging sciences to pursue evidence that is important to the regulators to clarify drug safety or efficacy both before and after drug approval.

Presently, we approve drugs based on the ability to detect large average effects of benefit or risk in studies of large populations. This approach is clearly inadequate and essentially unchanged for the past 50 years.

However, people vary strikingly in their response to most drugs – differences determined by the interaction of factors within their environment and their individual complement of genes. What matters most to people is not whether there is an average effect in a population, but how a drug will work in them.

The FDA is poorly placed to react, either to the challenges or the opportunities of this revolution in technology and medicine. Again, as pointed out by Dr. Cassell, our Subcommittee found that the development of medical products based on "new science" cannot be adequately regulated by the FDA.

Information from these new sciences is already providing an understanding of biological "networks" which, just as the interstate superhighway system lets us navigate the country, will allow us to understand more comprehensively how our body works in health and how and where these highways are blocked in disease.

The FDA is not on this superhighway; it is stuck on a rural dirt track trying to get from place to place in a Model T. It needs a major infusion of resource to give it modern, fuel efficient cars and to get them on that superhighway; it also needs the drivers who can cope with the traffic and roads of the 21st century. We propose that

it hires some drivers, but gets up to speed by renting the rest, part time, from the scientific fast lane – the academic sector.

It is unrealistic – short of the reintroduction of the military draft - to believe that the Agency could ever recruit a sufficient number of individuals skilled in these emerging sciences to assess and interpret the information from these new sciences.

The inability of FDA scientists rigorously to review these products will not only result in lost lives in some cases, but in others it will result in the failure of critical, innovative, life-saving medicines to reach the bedside in a timely manner. Failure of the FDA to advance to the 21st Century will have a major negative impact on the U.S. economy and the threatened pre-eminence of the U.S. in biotechnology and the biomedical and agricultural sciences.

For example, the only relevant expertise that the Agency has in house in genomics- the most advanced of the new sciences - is fragmented, uncoordinated and paltry.

By comparison, the FBI has invested millions of dollars in genomics and the NIH has an entire Institute of Genome Sciences. Even the CDC has made remarkable advances in applying genomics in multiple areas of public health, including food borne diseases. Likewise, USDA is more advanced in this area due to its own investment, but also its interactions with the National Science Foundation and the Department of Energy.

Sadly, the FDA lags far behind its sister agencies and is slowly playing catch up. It should be leading the way and setting the standards in applied genomics. Importantly, expertise in every other aspect of the emerging sciences is essentially nonexistent within the FDA.

Our Subcommittee concluded that science in the FDA is indeed in a precarious state. Because, as Dr. Cassell has emphasized, every regulatory decision that FDA makes is based upon science, this deficit must be addressed.

It is realistic and desirable that the Agency recruits or retrains a small *cadre* expert in the emerging sciences; however, their impact can be magnified if they are integrated into a larger network, a consortium of extramural scientists at academic sites - a Jet Propulsion Lab for the FDA.

Besides amplifying the science base of the Agency in the area of its greatest weakness, this JPL would provide a site in which the Agency expands its capacity to assess medicines using the most modern technologies and a framework for educational exchange. This initiative should also revolutionize our approach to drug development, hastening the time to drug approval and detecting more efficiently and faster problems with drug safety.

This initiative will empower the Agency by harvesting the talent of the US academic sector - the largest biomedical and bioengineering enterprise in the world and one funded largely by the taxpayer.

In summary, we concluded that the FDA is in crisis. Its ability to fulfill its mandate has eroded to a critical degree and will rapidly deteriorate unless they are provided appropriate resources and the Agency takes radical action.

Both the IOM and Science Board reports identify steps that will enhance greatly the ability of the Agency to guarantee the safety of the food we eat and the drugs and devices that we are prescribed. This will require provision of a substantial increment in resources.

However, best to do this while the levees are leaking rather than after the hurricane has hit.

1. IOM. The Future of Drug Safety. Promoting and Protecting the Health of the Public. Committee on the Assessment of the US Drug Safety System, Alina Baciu, Kathleen Stratton, Sheila P. Burke, Editors. The National Academies Press, Washington D.C. 2007 pp 1 -

2. http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf

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Mr. STUPAK. Thank you, Doctor.
Dr. Nordenberg, your testimony, please, sir.

STATEMENT OF DALE NORDENBERG, M.D., MANAGING DIRECTOR, HEALTHCARE INDUSTRY ADVISORY, PRICE WATERHOUSECOOPERS

Dr. NORDENBERG. Good morning, Mr. Chairman and members of the committee. Thank you for inviting me to appear this morning. I am Dr. Dale Nordenberg. I am testifying this morning on behalf of the Subcommittee on Science and Technology of the FDA Science Board for which I served as an advisor while I was an associate director at the National Center for Infectious Diseases at the Centers for Disease Control, responsible for informatics. When I became a managing director with PriceWaterhouseCoopers 4 months ago, I am not here this morning on behalf of PriceWaterhouseCoopers nor does my testimony in any way reflect the policies or positions of PriceWaterhouseCoopers. I am a CDC-trained medical epidemiologist and my area of expertise is health information technology. I have approximately 25 years of experience in this field. Accordingly, I would like to focus my comments on the FDA's information technology capabilities and the demands placed on them.

The subcommittee found that an information crisis is putting the agency's mission at risk. Although there is recent evidence of some progress in information technology of the FDA, there is a dual and compounding risk. The FDA is struggling with a too-slow modernization of its current information network while it is challenged to regulate products based on rapidly emerging sciences, particularly genomics, as you have heard from Dr. FitzGerald. Based on our evaluation, let me offer several examples of how the FDA's mission is being affected.

We found that the FDA's information systems were to a great extend obsolete, unstable and unsecured. For instance, 80 percent of network servers were beyond their recommended life. An example of the consequences of an unstable technology infrastructure is the e-mail outage that occurred during the FDA's response to a national foodborne outbreak of E. coli in 2006.

The FDA has lacked consistent leadership in information technology. The agency has had four chief information officers in the past 5 years. While the FDA's information technology professionals display commendable dedication, they need strong leadership, the resources to deliver quality and programs that build skills and expertise, particularly in the areas of emerging technology and science The FDA's information system which it depends on to evaluate product safety and efficacy are inefficient. Inspectors' reports are still handwritten and slow to work their way through the compliance system. The system for managing imported products cannot communicate with Customs and other government systems and often misses significant product arrivals because the system cannot even distinguish, for example, between road salt and table salt.

Clinical trials data were often buried in paper-filled warehouses. The FDA cannot electronically search must of its data, which

meant that possible side effects of drugs cannot be tracked and additional uses for existing therapeutics cannot be identified.

Finally, the agency lacks the capability to manage the complex data information challenges associated with rapid innovation. This can affect the FDA's ability to ensure the timely and safe introduction of products in such areas as nanotechnology, genomics, wireless products, medical imaging and cell-based products that could bring hope and results to people waiting for breakthrough treatment.

The FDA's information technology crisis can be solved. Adequate funding for information technology is crucial. The subcommittee believes that the information technology budget at the FDA must be increased. The overall IT budget for the FDA is approximately $200 million compared to approximately $500 million for the CDC, although the FDA regulates, as numerous people have mentioned, $1 trillion in consumer products and 80 percent of the Nation's food supply and is responsible for monitoring hundreds of thousands of sites that distribute it globally.

Increasing the budget would allow the FDA to upgrade and modernize its technology, support develop of its professional staff and establish the information systems it needs to fulfill its mission. Extramural investments are critical to stimulate the private sector to develop and implement integrated information-sharing networks that support both pre-market clinical trials as well as post-market pharmacovigilance activities to evaluate safety and efficacy and to support industry innovation. The subcommittee believes that the FDA affects the lives and well-being of Americans, the health of our economy and the security of our Nation as much as any other institution, public or private. Providing the FDA with the tools it needs to fulfill its mission is essential, and in the information age, ensuring that the FDA effectively deploys modern information systems is one of the most important tools of all.

Mr. Chairman, I thank you again for the opportunity to appear, and I would be pleased to answer any questions.

[The prepared statement of Dr. Nordenberg follows:]

Statement of Dale Nordenberg, M.D.
External Advisor to the Subcommittee on Science and Technology of the FDA Science Board

United States Congress Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

Hearing on Science and Mission at Risk: FDA's Self-Assessment
Washington, D.C.
January 29, 2008

Mr. Chairman and Members of the Committee: Thank you for the opportunity to testify before you this morning on "FDA Science and Mission at Risk," the report of the Subcommittee on Science and Technology to the FDA Science Board.

My name is Dr. Dale Nordenberg and I am testifying this morning on behalf of the Subcommittee on Science and Technology of the FDA Science Board. I am a pediatrician and a Centers for Disease Control (CDC)-trained medical epidemiologist. My area of expertise is health information technology, and I have approximately 25 years of experience in this field. I was invited to participate in the FDA Subcommittee on Science and Technology while I was the Associate Director for Informatics at the National Center for Infectious Diseases, CDC. While I resigned from the CDC four months ago to become a managing director with PricewaterhouseCoopers LLP, I am not here this morning on behalf of PricewaterhouseCoopers nor does my testimony in any way reflect the policies or positions of PricewaterhouseCoopers.

Information Technology at the FDA

Information technology at the FDA has three different purposes. First, information technology at the FDA provides an information and

communications infrastructure that is deployed to serve the needs of programs at the FDA and thus serves an operational role. Examples of this would include the computer network, e-mail system, financial and other administrative systems, and Internet connectivity.

Second, information technology at the FDA is encountered in regulated medical products, such as emerging wireless devices that can monitor heart rate and rhythm in real time as well as provide electrical shocks to the heart to treat abnormal rhythms. In this instance, the FDA must have the scientific and technical capability to review and regulate these products.

Finally, information technology at the FDA is a science and discipline that FDA scientists must use to assess the efficacy and safety of medical products as part of the regulatory mission of the Agency. This would include data and information modeling, analytic activities, implementation of evolving health information technology standards and health information exchanges to support pre-market clinical trials and post-market pharmacovigilance. This arena is often referred to as healthcare or medical informatics.

Information technology is absolutely critical to ensure data access, management and analytics related to inspections for food, drug and device manufacturing sites and for tracking foodborne disease outbreaks. The FDA must have the expertise to deploy or manage information technology in all of these three contexts in order to successfully support the regulatory science that enables the Agency to fulfil its regulatory mission.

Our subcommittee found that "an information crisis is putting the FDA mission at risk."[1] It further reported that "the IT situation at FDA is problematic at best — and at worst it is dangerous."[2]

While the subcommittee would like to acknowledge that it identified recent promising trends in IT activity priority setting at the FDA, the rate of progress is unacceptably slow. At this pace, there is a dual and compounding risk. Specifically, the FDA is struggling with the too-slow modernization of its current infrastructure while it is simultaneously challenged to develop the capability to manage the risk from rapidly emerging sciences, particularly genomics as you have heard from Dr. Fitzgerald; technology and threats such as bioterrorism; and globalization leading to a massive increase in imported products. Ultimately, the FDA must leverage regulatory and information science to support industry innovation while assuring the efficacy and safety profiles of products that it regulates.

Leadership and people

The subcommittee commends the dedication and commitment of FDA's IT professionals. Besieged by increasing complexity, there is a critical need to assist them by establishing professional development plans and providing access to continuing education. In addition, the Agency should explore extramural partnerships to help provide the required IT expertise.

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[1] "FDA Science and Mission at Risk" ("Report"), page 46
[2] Report, page 5

The subcommittee was surprised to discover that the FDA has had multiple chief information officers in recent years. Given the lack of consistent leadership in information technology, it is clear that even the basic IT infrastructure is presenting significant risk to the FDA's regulatory mission.

Information Technology Infrastructure

The subcommittee report states, the "FDA IT infrastructure is obsolete, unstable, and lacks sufficient controls to ensure continuity of operations or to provide effective disaster recovery services."[3] Specifically, the FDA technology infrastructure was burdened with 80 percent of network servers beyond the recommended life of the machine. Many people we interviewed described an environment of computers and servers distributed around the agency unsecured and without adequate recovery practices in the event of a natural disaster or other crisis. Many staff reported having had experienced loss of data. As a simple example of the consequences of an unstable technology infrastructure, the FDA's participation in the national *E.Coli* O157 outbreak in 2006 was hampered by outages in the FDA e-mail system that depends on the outdated FDA technology infrastructure.

Access to Data and Information (including data sharing networks)

The regulatory mission of the FDA is dependent on regulatory science; the discipline and methodologies used to evaluate the efficacy and safety of the regulated products evaluated by the FDA. Regulatory science, and thus the

[3] Report, page 51

mission of the FDA, is dependent on timely access to quality data and information.

Our subcommittee found that "the FDA's current critical information supply chains are, at best, inefficient, cost intensive and prone to promote errors in regulatory science due to the inability to access, integrate and analyze data. Incredibly, critical data resides in large warehouses sequestered in piles and piles of paper documents."[4]

In addition, the subcommittee found that "reports of product dangers are not rapidly compared and analyzed, inspectors' reports are still hand written and slow to work their way through the compliance system, and the system for managing imported products cannot communicate with Customs and other government systems (and often miss significant product arrivals because the system cannot even distinguish, for example, between road salt and table salt)."[5]

The FDA must invest in the development of both intramural and extramural health information exchange infrastructures for data sharing between health stakeholders such as payers, providers, pharmacies and patients to support all aspects of the critical path for medical therapeutics and devices, food safety, and other regulated products.

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[4] Report, page 48
[5] Report, page 5

Emerging Sciences and Threats

The subcommittee identified emerging sciences and threats as a major risk to its regulatory mission. Briefly, these emerging sciences and threats include: pan-omics, wireless healthcare, nanotechnology, medical imaging, telemedicine platforms, electronic health records – especially as they interface with medical devices – bioterrorism and globalization leading to the rapidly increasing number of imported products under FDA regulation.

The subcommittee found that the "FDA lacks the capability to manage the complex data and information challenges associated with rapid innovation, such as new data types, data models and analytic methods."[6] The proposed Incubator for Innovation in Regulatory and Information Science, described by Dr. Garret Fitzgerald, is an excellent environment to ensure that information sciences and information technology professionals at the FDA perceive and respond to the regulatory needs of rapidly evolving sciences and threats to fulfill its regulatory mission.

Budget Recommendations

The subcommittee believes that the information technology budget at the FDA must be increased. Based on publicly available information, the overall IT budget for the FDA is approximately $200 million — compared to approximately $500 million for the CDC, although the FDA regulates $1 trillion dollars in consumer products and 80 percent of the nation's food supply and is

[6] Report, page 50

responsible for monitoring hundreds of thousands of manufacturing sites distributed globally.

Increasing the budget would allow the FDA to upgrade and modernize its technology, support development of its professional staff, establish the information systems it needs to fulfill its mission and stimulate the development of data and information sharing among academic and private sector stakeholders to support innovation and regulation.

In summary, the subcommittee engaged in this endeavor with a strong belief that "The FDA, as much as any public or private sector institution in this country, touches the lives, health and wellbeing of all Americans and is integral to the nation's economy and its security."[7] Given this, "the nation is at risk if FDA science is at risk."[8] Without significant investment in information technology at the FDA, our subcommittee is firmly convinced that both the public's health and the nation's economic competiveness are at great risk.

It is the hope of the subcommittee that action will be taken to ensure the robustness of the FDA and thus its ability to fulfil its regulatory mission to protect the public's health and helping to speed innovation in regulated industries.

Thank you, Mr. Chairman, for the opportunity to testify this morning.

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[7] Report, page 1
[8] Report, page 2

Mr. STUPAK. Thank you, Doctor, and once again let me extend my sincere gratitude to this committee and the fine work you did. We are going to go with questions with members. We will go 5 minutes and we will move this along as we can.

Dr. Cassell, now that the report is accepted, your report is accepted, let me ask you, what really comes next? I notice on page 56 of the report, conclusion states, and I want to read it, "We therefore urge the FDA to develop a comprehensive plan that includes how and when the agency will respond to these recommendations and report that plan to the Science Board. We also recommend that this plan be aligned with the 2009 budget process in order to align the resources with the proposed response." Is the Science Board still meeting? I mean, you are saying in here "and to report that plan to the Science Board." It sounds like Science Board wants to continue to assist the FDA and American people in implementing your recommendations but are you still in existence? Do you still have some input into this process?

Ms. CASSELL. Thank you for asking the question. You may recall that our committee that issued this report was a subcommittee of the Science Board. While our subcommittee was considered to have issued a final report in terms of those areas that we reviewed, and so therefore we were dissolved as a subcommittee. Some of us still remain members of the Science Board. The Science Board obviously does continue to meet as advisory to the Commissioner. So as far as this subcommittee per se, we do not continue to meet or to have purpose since we were dissolved. However, we fully anticipate that the Science Board will be the body and it would be actively involved in the plan. You can rest assured, however, that the subcommittee will follow with great interest and are committed to help you and others do what is necessary to see that the recommendations of this report are implemented.

Mr. STUPAK. You said the Science Board expects to be involved.

Ms. CASSELL. Yes.

Mr. STUPAK. In order to be involved, the Science Board, since you are all outside of the FDA, you have to be invited by the Commissioner to work on this plan of implementation, does it not?

Ms. CASSELL. Yes. The Science Board is a permanent subcommittee, and Dr. Woteki and myself are members of the Science Board. So we will continue to be involved in the assessment of the FDA's plan when in fact there is a plan to address the recommendations of the report. I could just hasten to say that the subcommittee anticipated that a plan would rapidly be developed to address these urgent areas that we have pointed out.

Mr. STUPAK. The subcommittee expects that the plan would be rapidly implemented by the Commissioner. Have you discussed it with the Commissioner? Has he given you any assurances that the recommendations, final recommendations made, will they be implemented? What is his timeline? Has he indicated that to you?

Ms. CASSELL. No, not at this point in time.

Mr. STUPAK. Mr. Hutt, you mentioned—I want to make sure I have this right. The money the FDA should receive, you said it is a hollow government syndrome. The FDA basically receives about $1.6 billion a year, just over $2 billion when you get PADUFA fees for new drug applications. You said over the next 2 years you

should double that, so are you saying in 2009 the budget then including the user fees should be $4 billion and then the year after that be $8 billion?

Mr. HUTT. No. What I said was, over the next 2 years the entire budget should be doubled and the number of people increased by 50 percent. That is over a 2-year time so——

Mr. STUPAK. So in 2009 we would go from 2 billion to 1 billion if you did half of it, then in 2010 you would go the extra 2 billion or to 4 billion?

Mr. HUTT. Yes.

Mr. STUPAK. And use that money in a period of time to increase employees by 50 percent?

Mr. HUTT. That is correct.

Mr. STUPAK. OK.

Mr. HUTT. That is appropriated funds that I am talking——

Mr. STUPAK. Correct. Then you say maintain at 5.8 percent yearly to maintain increases in cost of living and other fees you have?

Mr. HUTT. Yes, because that is where Congress has failed to keep up with the times. FDA's budget has been basically over many years relatively flat. It hasn't kept up with inflation.

Mr. STUPAK. I agree, and 100 more statutes, as you pointed out, in the last 20 years.

Mr. HUTT. Yes.

Mr. STUPAK. Let me ask you this then. I am a little confused. There is some concern expressed that the Science Board overstepped its mandated because it focused on review, not merely on scientific concerns at the agency but also the lack of resources that Mr. Hutt has pointed out, and in your report it says, I will quote again, "Although this subcommittee was asked to review gaps in scientific expertise and technology and not to assess available resources, it rapidly became apparent that the gaps were so intertwined with 2 decades of inadequate funding that it is impossible to assess technology without also assessing the resources," which Mr. Hutt did. So what is the rationale for asking you to do your work, to point out the scientific shortfalls but not discuss the resources necessary to improve that scientific resource or base of knowledge since every decision, as you said, Dr. Cassell, at the FDA should be based on science?

Mr. HUTT. Well, let me respond to that. At the first meeting of the subcommittee, I pointed out that it would be a disconnect to talk about pure science and not to talk about resources. That is the reason that I undertook to write a separate report on A, resources, and B, responsibilities. I will let Dr. Cassell to her views on this also.

Ms. CASSELL. Yes. We were in fact discouraged from looking at the resource issue but as Mr. Hutt said, it was rapidly apparent that it would be almost criminal to identify the gaps without also trying to address the resource issue. Therefore, we did give this a lot of attention in terms of our review.

Mr. STUPAK. My time is up, but I am sure we are going to come back for another round so I will have a chance to ask more questions. Just one comment, Mr. Hutt. If we go 5.8, double that amount to 5.8 each year, we are the authorizing committee, I am sure we are happy to do it but I think the appropriators will have

a different view on it, and I would think the Commissioner would love you on his Science Board, especially with those numbers and the assistance you are willing to put forth.

Mr. HUTT. Well, I am not a scientist so he will——

Mr. STUPAK. But you are a financial man, which they need obviously.

Mr. Shimkus for questions, please.

Mr. SHIMKUS. Thank you, Mr. Chairman.

A couple things. My response on most Federal Government operations is, we always over-promise and we always under-deliver. That is endemic of government and it is unfortunate and I think the report kind of highlights that and it is a challenge that we have to face.

Dr. Woteki, in my opening statement I mentioned the 600 investigators that we moved after September 11 and they are now gone. Can you talk about that real quick, where they went to, why, what happened?

Dr. WOTEKI. Well, quite frankly, that is not an area that we looked into. We have the statistic on——

Mr. SHIMKUS. But you were nodding when I mentioned that.

Dr. WOTEKI. Yes, because it is, I think, a good indication of the resource constraints under which FDA is operating. The fact that the bump-up in inspectors, which was badly needed, that they were not able to maintain that in subsequent years is a symptom of how deeply stressed they are for resources.

Mr. SHIMKUS. Briefly, Mr. Hutt?

Mr. HUTT. Mr. Shimkus, it was a simple matter of appropriations. The appropriations were not there to sustain that number of inspectors and therefore they were lost.

Mr. SHIMKUS. Over-promising, under-delivering. Now, I was at another meeting obviously but Mr. Hutt called you—is it Cassell or Cassell? What is the proper pronunciation?

Ms. CASSELL. It is Cassell.

Mr. SHIMKUS. OK. The first question I have for you is, what are the top three areas of the FDA where you believe there could be bipartisan support for significant funding increases?

Ms. CASSELL. I believe first and foremost, no one could argue with the urgent situation of the information technology situation. That has to be corrected. Secondly——

Mr. SHIMKUS. And if I could jump in real quick. When I talked to my constituents and they say what can Congress do in an election year and smaller objectives. Information technology is I think something that in a bipartisan way there could be movement on. Continue, please.

Ms. CASSELL. The second would be the food importation situation and associated food safety situation. The other thing would be the drug safety and the recommendations that the IOM, the Institute of Medicine, recommended that be put in place so that we have a safe drug surveillance system. While the PADUFA funding did increase funds for those recommendations, they certainly fall short of what is needed to fully implement them, and we think this is a very serious problem.

Mr. SHIMKUS. Let me follow up with you on the PADUFA and the user fee question. Are there avenues—I mean the appropria-

tions is going to be the appropriations battle and I don't think it matters who is in charge. A slice of the pie is going to be always difficult. PADUFA has been successful. Are there other ways that we can use a system like that in other areas to—I mean, I think there is actually more accountability too. When you have the user folks paying in, they are going to make sure that there is a better response. Is there another way in which we can use that?

Ms. CASSELL. I think that perhaps Dr. Woteki might address that.

Dr. WOTEKI. Yes. The Center for Food Safety and Applied Nutrition and CVM have not had a user fee situation. They have relied on direct appropriations, and I have to admit that as Undersecretary for Food Safety in a different administration, I testified on behalf of user fees to support our inspection area for meat and poultry. At that time it was not a viable option and at this time it arises again with respect to support for the food side and the veterinary side of FDA. The one thing that we did conclude in our review of the financial situation with respect to FDA in these two centers is the need for new appropriation and that that has to come from Congress.

Mr. SHIMKUS. OK. It will be interesting to see what my livestock folks have to say about some of that.

Dr. Nordenberg, it kind of goes back to the technology. Are you familiar with FDA's automated import entry system, Predict, and did you evaluate this in your review?

Dr. NORDENBERG. I am not familiar with that system.

Mr. SHIMKUS. I think we should probably throw that in as far as concern from the subcommittee and evaluate that with respect to these concerns.

With that, my chairman is not here so I could gavel it closed but I think I would get wrestled. I yield back my time, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Shimkus.

Mr. Melancon for questions.

Mr. MELANCON. Thank you, Mr. Chairman.

I guess I have got one general question for the entire panel. There have been numerous reports that have spoken to the demise of FDA over the period of years. Being the Cajun I am and with the storm effect, and the gentleman just reminded me of a story. After the storm, Boudreau was at his house and the water was up to the front porch. It was continuing to rain and a levee had broken and a neighbor came by in a boat and said, you know, get on board, I will take you with me. He said no, I am going to wait for the Lord to save me. And then the next boat came by and he was on the second floor and the next boat came by, he was on the roof. Finally he is on the top of the chimney and a helicopter came by and he said thanks but I am waiting on the Lord. He got to heaven's gate and he was upset and he wanted to know why the Lord didn't do anything and the Lord said I sent three boats and a helicopter, what else do you need.

I mean, we have seen these reports. In each of your minds, what exactly would you suggest to the Congress, to the Administration or to anyone else that we can do or that can be done to put right this agency and move it in the direction that we have to move it

to make it a viable agency to be responsive to the needs of this country?

Ms. CASSELL. Very quickly, that was the most appalling thing to our committee, I think, that we observed and that is, that what we were finding certainly was not new. It had been reported in the past as long ago in terms of food safety as we heard in the 1950s and in a 1991 report. So the question is why in fact have these recommendations not been implemented. One obviously is resources and lack of resources to implement them. That is one thing. So what can we do? We can make certain that we do get increased appropriations. But in addition to that, I would say that this committee as well as the Science Board can request and should request frequent updates in terms of what has been done to implement the recommendations or to find out why they are not being implemented and not to let this report and other reports that you will hear about this morning sit on a shelf and we are back here 5 to 10 years from now basically having the same conversation because I think by that time we won't have an agency to really talk about. Mr. Hutt has recommended there be another similar review in 5 years. Our report strongly recommends that there be external advisory committees, standing committees that would review processes continuously within each of the centers and to review progress in terms of implementation and to critique advances, and I think this has been one of the major deficits in the past. There hasn't been that external peer review that other agencies do utilize, welcome and in fact I think don't get in a situation that we currently have with the FDA, and I think Mr. Hutt also has some——

Mr. MELANCON. And I would like to ask to have everybody continue that line, but let me ask, do you or anyone have any knowledge of these reports being done and they are just put on the shelf or did the administrators in the past or present take them, go to OMB, come to the Congress appropriations or did they just ignore the vital signs were bad?

Ms. CASSELL. I am aware of one recent report in 1997 called the Horn report that actually specifically looked at science within the agency and have been told that in fact it really never saw the light of day. I am—I don't know for certain about previous reports and conversations with OMB but a lot of what the Horn Report recommended quite honestly would not have required a lot of additional increased resources.

Mr. MELANCON. When in the light of day was suggested that this report not show up, whose suggestion was it that it not appear anywhere? Do you have knowledge of that?

Ms. CASSELL. I don't know. I don't know, but I can just tell you that was one of the great concerns of our committee. You can imagine the busy people I talked about. I had to continually assure them our report would make a difference, and we did repeatedly ask Commissioner von Eschenbach, will this report be taken seriously, in fact, will you consider the recommendations. This was before we had specific recommendations but before investing ourselves in the task, we wanted to be certain it wouldn't end up like previous reports.

Mr. HUTT. Mr. Melancon, the basic problem is that every citizen in the United States assumes that our oldest and most important

Federal regulatory agency is out there doing its job. No one knows that Congress has had a flat budget. No one knows our Field Force has been decimated. We assume that there are FDA inspectors all across the country, and when they are lost, as they have been, there is no major story about it. It is not the kind of story that our news media report every day. So it is up to all of us, everyone in Congress on a bipartisan effort, everyone in this room, all of us in this committee, to get the word out there that this is a serious problem and to bring it to the attention of the public so that everyone knows what the situation really is.

Mr. MELANCON. Any special specific recommendations or is that included—I mean, other than money, and we know that is one as the chairman had indicated——

Mr. HUTT. Well, I call on our national press, many of which are in this room and are extremely fine people, to focus on the budgetary aspects of FDA and to delve down deeply into, as we did, each of the centers to delve down into the functions within each of the centers such as Dale said, the Field Force. To me, the heart of FDA is the Field Force. They are the people out across the country. They aren't sitting in Washington. They are in every city in the country trying to make sure that our food is safe and our drugs have the integrity that they should.

Ms. CASSELL. But actually the Office of Regulatory Affairs, which would include some of the aspects of the Field Force, has never had an external review as far as we know.

Mr. STUPAK. Thank you.

Mr. Burgess for questions, please.

Mr. BURGESS. Thank you, Mr. Chairman.

I guess, Dr. Woteki, let me ask you and perhaps Dr. Cassell can address this as well. When we had our food safety hearings earlier or rather last year, between the USDA and the FDA oversight over food products in this country, for foreign countries, USDA has 20 percent, FDA has 80 percent. Within the USDA, the concept of equivalency exists. In another country if they don't do things exactly like we do, it still has to be equivalent to our processes, and FDA, to my understanding, does not have that same concept of equivalency. Is that something that the FDA needs as far as the oversight of imported foods?

Ms. CASSELL. Cathy, I think you are in a better position.

Dr. WOTEKI. Yes, and I know Peter as well has strong feelings about this, but you are absolutely right with respect to the difference in the authorizations that FSIS has with respect to FDA for imported foods. Under the meat and poultry inspection acts, FSIS requires before any country will export meat or poultry products to the United States that they, one, have an equivalent system of inspection from a legal as well as from a functional perspective, and secondly, an inspector must actually visit the plants from which the meat that will be exported in which they are slaughtered and processed. So then in addition, the imports undergo an inspection when they actually reach our shores so there is at least two levels of inspection that occur for meat and poultry products.

Mr. BURGESS. At the USDA?

Dr. WOTEKI. That is at USDA. FDA is quite different. Their authority starts at the shore, and I understand from reading some

interviews with the Commissioner that there are some ideas being proposed to strengthen the FDA presence overseas. I don't know the specifics of what the regulatory authority is under which they will be doing it but I do think it is appropriate to strengthen FDA's presence overseas.

Mr. BURGESS. So if they need legislative authority to strengthen that oversight overseas, that would be something you would be in favor of us providing?

Dr. WOTEKI. Most definitely, yes.

Mr. BURGESS. Let me just ask you this because we heard this testimony in one of our hearings earlier this year, and I was just astounded. This is just a little bit off topic, but if someone, a company that is importing from overseas finds that they have a supplier with a problem, they are not obligated to report to other suppliers that they have found a problem so if their competing entities are using that same importer, the problem may not be stopped. Furthermore, they are under no obligation to disclose that to the FDA or to any regulatory agency, and that seems like a very weak link in our chain that if we have got someone overseas who is actively engaged in the process of importing food over here and they find that one of their suppliers has put whatever in—has contaminated a product with whatever, I guess because of competitive reasons they don't want to disclose that to other importers but it seems like there has got to some way, some reporting mechanism so that the agency charged with keeping us safe can know that and at the present time I guess there is no mechanism in place for that to happen. Is that correct?

Dr. WOTEKI. Well, Peter can also intercede on that question as well. I would just like to point out that the Grocery Manufacturers Association has put together a proposal for strengthening food safety and does deal specifically with this issue of reporting requirements and I would urge you to consider their proposals with respect to strengthening FDA's authority with respect to imported foods.

Mr. HUTT. Mr. Burgess, let me just briefly comment. First, FDA has current statutory authority to inspect establishments abroad. That is in the statute. There is no limitation about inspecting in the United States and in fact FDA inspectors do go abroad and do inspect today. The problem is, there aren't enough of them to really do the job. That is the problem. Once again, it's not statutory authority. It is resources. And second, I agree completely with Dr. Woteki that a voluntary program by the industry to address some of these would be an extremely good thing for Congress to review because if industry can do it by itself, it will do a much more thorough job more efficiently and quickly.

Mr. BURGESS. You know, in general I would agree with that philosophically but again I was just astounded that that does not already occur, and in my mind it raises a question if there should not be some obligation, hey, we found this in this stuff that we are importing and report that to whatever the regulatory agency is, whether it be FDA or USDA. It just seems common sense that our agency would require that type of reporting if a serious problem with a foodborne illness or contaminant in a food product was identified.

Mr. HUTT. Well, sir, that is a very complex issue because if you are going to set up a system of that kind, there will have to be a whole new mechanism, far more resources in FDA in order to implement it, resources that might better be spent on other things. But if industry can do it itself, then the government resources will not be needed and can be used frankly for better use.

Mr. BURGESS. Again, I will concede that philosophically I would agree with that but it doesn't seem to be happening and my concern is that if someone finds a problem, they just keep quiet about it and then the poor FDA is left trying to catch up the best they can. So to put it in the obligation that under certain circumstances this voluntary program that I welcome the Grocery Manufacturers Association setting up but under some circumstances they are obligated to take that data to whatever the regulatory is.

Mr. Chairman, I know I went over. I will yield back.

Mr. STUPAK. Would you care to answer?

Mr. HUTT. Well, no, I think we could continue this discussion perhaps at a later time.

Mr. STUPAK. Mr. Inslee for questions.

Mr. INSLEE. Thank you. I wanted to ask the panel about this medical device scam disaster we have a little bit, and you heard me talk about a couple tragedies that have befallen some folks and I want to talk about this one situation to just put it in context. This article in the Seattle Times, the report I was reading is about a fellow who in the 1980s developed a machine he said could cure a host of illnesses, allergy and cancer. He called it the EPFX. His name was William Nelson. The USDA basically shut him down and ordered him to stop selling the machine. He refused. He was indicted on felony fraud charges, left the country and he is now in Budapest, Hungary, and one would like to think that was the end of the story, success, mark of achievement by the FDA but we now find out that he is in Budapest, Hungary, selling these devices worldwide. He sold 10,000 of them in the United States, 10,000 of them, and here we have a situation where the FDA has identified a known problem, a known machine, a known potential disaster for people and there are 10,000 of them that we haven't succeeded in stopping this from happening. Now, to me, that is just extraordinary to think that such a known problem could exist. It is one thing to have a product, an adulterated product we didn't know about. It is another one to have it known and having a wholesale failure to solve this problem. Now, that failure could result from I think multiple circumstances. One, failure to have enforcement agents available in the field, as Mr. Hutt suggested. Two, allowing some loopholes and there are other stories of how people have used the independent review boards as a loophole to continue to allow marketing while supposedly it is in a clinical trial. Third, just a lack of IT resources to be able to track this and see where these devices were but if any of the panel could help us understand what you believe would be the source of that failure, I would like to know. Mr. Hutt?

Mr. HUTT. Mr. Inslee, I am as horrified as you are by that story. As a personal matter, during my tenure at FDA I drafted the medical device amendments of 1976 and that statute had substantial legal authority for FDA to stop exactly what you are describing,

and I am sure Dr. von Eschenbach is as horrified as both of us. The problem is FDA enforcement resources. The agency can't be cut back in terms of its field personnel, which, as I said a few moments ago, is the heart of compliance activity in the agency. We can't cut those back and then expect that they will be able to solve the problem that you described. So the answer is to strengthen the FDA field. That is why I feel it should be doubled in the course of 2 years, over the next 2 years. Most of those resources would go to the Center for Food, Center for Veterinary Medicine and the FDA Field Force where they have been cut back over the years so that this kind of problem could be dealt with immediately. Obviously it wasn't dealt with. It wasn't dealt with effectively at all. It should have been. But I urge you to look at the cause of why it wasn't dealt with and it is the lack of appropriations from Congress.

Dr. WOTEKI. I might also add that in the area of dietary supplements, there are many false claims that are being made as well, and it is an area where again because of priorities and resources, the agency can't address.

Mr. INSLEE. Let me ask you if there is another problem here, and that is, in reading these horror stories, what I read a lot about, there are devices that have been originally approved as biofeedback devices or devices involving some seemingly benign-sounding mechanism but then go into a person who uses it who says this is going to cure cancer, this will cure chronic fatigue, this can alleviate your allergies when you have the individual using the device making these representations. Do we have a problem in the lack of consistent enforcement between the FDA and the locals, because a lot of these local people are under local licensing as physical therapists or counselors or, you know, whatever. Do we have a problem in those two agencies not working hand in glove in that regard?

Mr. HUTT. Well, the local, State and food—State food and drug officials coordinate very, very closely with the Food and Drug Administration. Indeed, there is a specific provision in the Federal Food, Drug and Cosmetic Act that allows FDA to commission the local, State food and drug inspectors to act on behalf of FDA. So once again, there is not a lack of authority, but in order to make that work, FDA needs funds to help the State, local people do that job and they don't have sufficient funds to do that.

Mr. INSLEE. By the way, do we have extradition authority on this, these kind of cases? Here is a fellow who has been indicted on felony charges. Do we not have extradition authority? Do you know?

Mr. HUTT. FDA has no extradition authority but the Department of Justice may well.

Mr. INSLEE. Thank you.

Mr. STUPAK. Mr. Walden, do you have questions? It is your turn.

Mr. WALDEN. I appreciated the witnesses' testimony and answers to the questions. I have been listening to some of that in the background.

I want to follow up on a couple of points. Let us take for granted that there is a need for more money in the agency for a moment and let us say, Mr. Hutt, Dr. Cassell, others, that money is all shoved over here to FDA. Is that just going to solve the problem? Too often government just says here is the check, gee, we are

solved. Are there other deficiencies within the agency that need to be met? I have been in small business 21 years. You know, sometimes it is cultural, sometimes it is the people. Dr. Cassell, address that.

Ms. CASSELL. Yes. Our committee felt very strongly that just adding the additional resources would not solve all the problems. However, without them, you actually could not expect to bring about correction of the major deficiencies. One is structural, and that is, you heard Dr. FitzGerald say there needs to be a strong chief scientific officer. During our review, there was a deputy commissioner appointed but that person's title is deputy commissioner and chief medical officer. We would argue that it would be almost impossible, we think, to have a person that would be the chief medical officer of the agency and in addition be the chief scientific officer. Then we also made the recommendation that within each center there needs to be a strong scientific leader, that these individuals should be responsible for helping to develop in fact the science infrastructure, strategic plan for the different centers and a very strong vision communicated in terms of what is the science base of the FDA, how important is it within the FDA, and also then to be able to communicate and articulate that vision so that in fact you would be able to muster the appropriate resources. So that would be one of our strongest recommendations. The other, I might hasten to add, has to do with the recruitment and retention of the scientific personnel. FDA has twice the turnover——

Mr. WALDEN. I saw that in your testimony.

Ms. CASSELL. Twice the turnover rate than other agencies, and not only that, but two of the center directors, the two largest ones, in fact, left their positions during the review.

Mr. WALDEN. Thank you.

Dr. Woteki, I had the opportunity to tour the Banfield Pet Hospital facility in Oregon, and I know Mars owns Banfield.

Dr. WOTEKI. Yes.

Mr. WALDEN. I was very impressed with the IT system that you all used to care for animals and track their healthcare. Then I read this report about FDA's typewriter IT system, if you will. I mean, we are going back several generations. Can you compare and contrast how you all operate an IT system and is that—I mean, I would like to see that for human healthcare, by the way. It is great for animals.

Dr. WOTEKI. Exactly.

Mr. WALDEN. Can you talk to us about that and your recommendations and that side of this equation?

Dr. WOTEKI. In essence——

Mr. WALDEN. That seems to be the other important part.

Dr. WOTEKI. In essence, the Banfield system that you are referring to is the computerized hospital record but for your pet. Each physician, or each veterinarian who practices in the Banfield system as he or she is examining a cat or a dog is entering all of his observations or her observations into this computerized system. So it does enable Banfield to be able to do epidemiological types of studies as well as surveillance on the pet population. So it is a very valuable resource and one in which hospitals for people have also for many years had an interest in creating a similar type of system.

From the FDA's perspective, as you heard, there are many aspects of the IT system that need to be addressed, and when you start de novo with a company like Banfield did in building their system, it is easier to do than to step into an agency that has been for over its whole history of introduction of computer systems building separate systems——

Mr. WALDEN. Right, that don't talk to each other.

Dr. WOTEKI [continuing]. To address each individual center and even programs within the center.

Mr. WALDEN. And one of the things we found in other oversight hearings is that some of the reports of drug interaction, problems that people have had, seem to go off into a wasteland and never get integrated in, and that is what struck me about the similarity with what you all do at Banfield is that integration. It seems to be lacking not only at FDA but in other agencies. Would it be better just to start over with a new system?

Dr. WOTEKI. Well, Dr. Nordenberg would be more competent to answer that question.

Mr. WALDEN. Thank you.

Dr. Nordenberg?

Dr. NORDENBERG. This question comes up frequently, and the language around it is telling. People often speak about a system but in fact there is no single system. I reflect back on the Internet. Is the Internet a system? It is more of a system of systems that nobody owns. What the country needs and what the FDA needs to catalyze the development of is a system of systems that will share the type of data you are talking about for purposes of clinical trials and for purposes of post-market pharmacovigilance to look for adverse events. It does that by investing in extramural activities to stimulate both academia and private industry, the hospitals, the payers, whoever might be a stakeholder in the type of data that we need to collect so that at any moment they could look at that data and say oh, this product is out there and this is what is happening to our people. Now, one of the peripheral components is exactly what you are talking about. That component would be the electronic health record in the case of human beings but in the case of animals, it will be the animal health record, if you will.

Mr. WALDEN. Thank you. I know my time is expired, Mr. Chairman. Thanks for your indulgence.

Mr. STUPAK. Thank you. We are going to go another round here. This is a great panel and I have a number of questions.

Dr. Nordenberg, there is a lot of questions on IT. Let me ask you this question. I think we have had four or five IT officers in the last few years at the FDA so everyone brings a different system with them and none of them working together. So doesn't it make more sense to have the FDA's IT budget and that of the CDC and NIH targeted at the department level and the FDA, the CDC and the NIH become clients of HHS and you can then predict concepts at the front end of all agencies. Then if there is a consolidation of food agencies under HHS, which is being proposed by Congresswoman DeLauro, and a separate drug and device agency, you do not have to duplicate the IT systems for managing important programs for foods, drugs or devices. Does that make sense?

Dr. NORDENBERG. The requirement at hand is very complex. The ability to collect data from all the different points of contact, if you will, is something that no agency or department can control. In fact, if you look at the Nation, 85 percent of our infrastructure is privately owned. We talked about preparing this response. Eighty-five percent of the infrastructure is privately owned. So the question really is, how does government stimulate the development of these capabilities at the point of care, for example, in terms of electronic health record and how does it influence development of the interoperability or the ability to exchange or integrate data, and in fact HHS is leading an effort out of the Office of the National Coordinator for Health Information Technology. If you go back 5, 10, 15 years ago, we didn't have the technology required to do what we are talking about so some of this is organic and inherent within limitations of the FDA, the changes in leadership, the lack of resources. Those type of things, if we can fix those we can rapidly fix the intramural, the intra-agency challenges. But if you want to affect the extramural, these data-sharing networks, these require investment again in academia and in the points of care, if you will, so they can evolve their capability. For example, we not only would deal with HHS as a department but Homeland Security would be important here in terms of we have to deal with Customs so then you bring it above those two departments so really the overall standards are set at a department level but the various agencies interact with their stakeholders and then hopefully there's interoperability.

Mr. STUPAK. Well, that is what I was suggesting. If we had a department and each agency could plug in, I just think you would——

Dr. NORDENBERG. Within each agency there is that—there is where the comment about the chief information officer is so critical. For example, HHS has a chief enterprise architect——

Mr. STUPAK. Correct.

Dr. NORDENBERG [continuing]. That interfaces with each of the——

Mr. STUPAK. Agencies.

Dr. NORDENBERG [continuing]. Agencies with their chief enterprise architect and there is that attempt to standardize. But this going to be—this is a large, complex project moving forward.

Mr. STUPAK. Dr. Cassell, on December 1 last year, the New York Times ran a piece on the Science Board report entitled "Advisors Say FDA Flaws Put Lives at Risk." Your report on page 6 also notes that lives are at risk. How are lives at risk? Give us an example that we could identify with, clearly identify with.

Ms. CASSELL. I think that you and all of us have unfortunately read about these in the news over the last year and a half, many of them related to foodborne illnesses. Many in fact have been associated with situations where we should have been able to perhaps better predict the risk as well as the benefits of new therapies, and I would say that if in fact you look in almost in every area in terms of the deficiencies that we have pointed out, we say lives are at risk because you don't have the appropriate checks and balances in place. One of the things that was pointed out in the self-assessment by FDA was indeed the fact that vaccine adverse events re-

ports today are still being reviewed manually. We also made the observation, as have others, that there has been a tremendous increase in adverse drug events that as Mr. Hutt found when he was putting together his white paper, in fact while you have this tremendous increase in adverse-event reporting you did not increase the number of the staff within FDA that were reviewing those adverse events so that in fact the time being spent on each adverse-event report to try to better understand what was going on were far fewer. I think Peter actually tried to calculate the exact number of minutes that could be spent on ones today versus several years ago. Collectively then, I think you can't reach another conclusion other than the fact that American lives are at risk in terms of almost every area where FDA oversees products. Now, mind you, this is not to frighten people to the extent today that you stop eating or stop taking your medications but rather to say in fact it is urgent the deficiencies that have been noted and they have to be corrected, to no longer delay them waiting on yet additional reviews of yet additional committees. I think the point is that they are—we are at the breaking point, if you will.

Mr. STUPAK. Well, 6 years ago I wrote legislation saying put an 800 number for adverse effects, not to scare anyone, just so that it can be reported. That doesn't do us any good if—again, FDA still hasn't put out the 800 number. We are still waiting 6 years later. But even if they did, there is no one to receive it or to review the documentation for doing it by hand.

Let me ask each of you, and if you can do it quickly because my time is up, in 60 days if we were to come back and have Commissioner von Eschenbach come back before this committee, instead of being on the third panel I will put him on the first panel if he tells me how he is going to implement your recommendations. What is the one recommendation you would say do in the next 60 days that would make a significant change at the FDA and how they are doing? If they had 60 days, what would it be? Dr. Cassell, I will start with you and go right down the line.

Ms. CASSELL. I would certainly like to hear from my other colleagues. I would put IT at the first of the list, what would be done to actually address the recommendations that have been pointed out by the subcommittee. Right underneath that I think you have to address this issue of recruitment and retainment of the scientific personnel that are needed.

Mr. STUPAK. OK, IT, recruitment of scientists, get back the science base.

Ms. CASSELL. And then the importation issue.

Mr. STUPAK. And importation.

Mr. Hutt?

Mr. HUTT. I approach it somewhat differently. FDA can do relatively little to implement our report, in fact, almost nothing, without additional funding. It is up to Congress. It is not up to FDA to help solve this problem. FDA is ready to change, I am certain of that. But if you say it is the old issue that one of the members of the subcommittee, of your subcommittee said, telling people to do more with less is impossible. I believe Mr. Dingell made that point. They are going to do less with less, and that is what they have been doing for the last 20 years. So asking them now to im-

plement a report of our nature on the basis of what they have today is asking the impossible.

Mr. STUPAK. Correct, but if they don't submit a plan to Congress and ask for it, the appropriators are going to look at them and say you are not serious about it and——

Mr. HUTT. That is correct.

Mr. STUPAK. If you go back and look at the budget——

Mr. HUTT. I agree——

Mr. STUPAK [continuing]. There have been no increase requests.

Mr. HUTT. The one thing they could do is lay out a blueprint and they could lay out, if they are permitted, and they may not be permitted, to put money against everything that they want to do.

Mr. STUPAK. The blueprint has to be with dollars just like you. You were told to look at this report but you are not allowed to look at the resources necessary. You can't have one without the other.

Mr. HUTT. But Mr. Stupak, this is the real world. The Commissioner can't go against the President's budget. The Commissioner can't come in here and say the President has set this budget, he is wrong, I want a higher budget. That is unrealistic. That is not going to happen.

Mr. STUPAK. And if he is bound by the President, then how do we break that impasse?

Mr. HUTT. I can't solve that problem.

Mr. STUPAK. We are working on it.

Dr. Woteki?

Dr. WOTEKI. Well, my one recommendation was going to be that you request a forward-looking plan that would say if you are going to be appropriated this number of dollars, how would you use it, and then use that to provide the appropriate oversight.

Mr. STUPAK. Dr. FitzGerald?

Dr. FITZGERALD. Yes. I believe that a plan denominated with dollars is what is requested, and I think within our report we have had the temerity to suggest ways in which the problem can be fixed.

Mr. STUPAK. Mr. Nordenberg?

Dr. NORDENBERG. I would also say that the plan is critical. I would also say that needs to be prioritized so that aspects of the technology of the infrastructure that are currently unstable and at risk should be identified and remediated as soon as possible. I look at the PADUFA language here for the IT plan. They talk about a 12- to 24-month period of focusing on completing plans. Twelve to 24 months is way too long. There needs to be an immediate assessment of things that are unsecured and unstable and have those remediated.

Mr. STUPAK. Thank you. My time is up.

Mr. Burgess?

Mr. BURGESS. Thank you, Mr. Chairman. I feel obligated to say these hearings that we have where we have the head of a Federal agency in, we require that person to spend the whole day with us. I think that structurally is unfair and I just want to register my displeasure with how these hearings are structured. This is an individual who as we heard from testimony today, he is got an enormous job on his hands and we are tying up a full day, and this is the second time we have done that, and I for one want to register

my displeasure. I don't want to see us repeat this trajectory again in the future. If we have to call the head of a Federal agency in, let us afford him the due courtesy that we would the head of any Federal agency, allow him to give his testimony first and then get on with the business of running his agency.

Mr. STUPAK. I will give you my word that in 60 days if we have another hearing and have Commissioner von Eschenbach come back to implement the plan that we are hearing about today, I think it is important——

Mr. BURGESS. Reclaiming my time——

Mr. STUPAK [continuing]. That if he does it—I will extend your time—then I may put him on the first panel, and then he can tell us how he is implementing it. How about that?

Mr. BURGESS. It should be unequivocal that he is on the first panel every single time he testifies before this committee or any other, the same that would be afforded to any Administration, whether Republican or Democrat, regardless of who is in charge in the House of Representatives. This is a foolish way that we are going about this, and personally I just take great umbrage to it and I think it reflects poorly on the subcommittee, and that is something that I think is a serious problem. We have an approval rating of 10 percent right now, for crying out loud. How are we ever going to do—we have no political capital left. How are we ever going to do the things that have correctly pointed out to us when we continue to behave in this manner?

Dr. Nordenberg——

Mr. STUPAK. The way to do it is to have oversight of FDA, and again, 60 days to have Commissioner von Eschenbach back and see if he is implementing his plan——

Mr. BURGESS. Reclaiming my time. No problem with oversight——

Mr. STUPAK [continuing]. And we will have him——

Mr. BURGESS [continuing]. But for heaven's sakes——

Mr. STUPAK [continuing]. On the number 1 panel.

Mr. BURGESS [continuing]. Let us do it correctly.

Mr. STUPAK. We are.

Mr. BURGESS. There is no precedent for doing things this way.

Dr. Nordenberg, let me ask you a question about the information technology because that comes up all the time. How did we—did we just buy the wrong equipment originally or did we buy the right equipment and now it has degraded over time because we haven't invested the proper amount in maintenance or software upgrades? Where is the difficulty? I mean, it seems to me—let me just tell you my problem. We hear from people on both sides of the dais in this committee and in fact in the full Congress that the way to solve our problems with healthcare in this country is that every doctor needs to come up in the 21st century with health information technology. So we propose vast unfunded mandates on our medical personnel across the country and we can't even do it right in a Federal agency. I mean, they are going to come back to me and say look, this hearing you just had and you couldn't even do it right within probably the most premiere Federal agency in the United States government. How are we to go to our physician colleagues with a

straight face and say you need to upgrade your computer technology? How did it get like this within the FDA?

Dr. NORDENBERG. So as I mentioned, if you look back 5, 10, 15, 20 years, everybody I think is very much aware of how rapidly technology has evolved. You take a large organization or enterprise, they start to buy technology, they start to implement it. The ability for them to keep pace with changes in technology is very difficult. So when we——

Mr. BURGESS. Let me stop you there for just a minute. Is that because they are a bureaucratic Federal agency or because it is just difficult to keep up with technology?

Dr. NORDENBERG. It is difficult to keep up with technology. However, for the reasons you mentioned, this agency, which is one of our premiere agencies in this country, which is so critical for protecting the people in this country as well as for helping industry innovate and bring that innovation to market, it is critical that this enterprise as much as any stays abreast and so when we look at our recommendations, it is possible to go out and make an investment, and our report actually states that we believe that there are good people on the ground and with the appropriate investment they can modernize their basic infrastructure. There is no reason why that cannot happen and can't happen expeditiously. On the other hand, the extramural challenges of building these complex, multi-partner data-sharing networks is not a quick fix. On the other hand, it is absolutely critical because those networks will be the networks that enable the FDA to exploit regulatory science and to evaluate the safety profiles and efficacy profiles of the products that it regulates.

Mr. BURGESS. Yes, and that is—pardon me for interrupting because my time is going to run out but that is exactly what concerns me. We sat here last June in a very self-congratulatory time talked about what a good job we were doing as far as database management and providing the FDA with the tools it needed for database management so that, as you point out, the pharmacosurveillance and post-marketing studies can go forward, and now you are telling us it doesn't even exist?

Dr. NORDENBERG. So essentially what I would say is the way I look at this problem, you have to look at it as a supply chain problem. People—for example, the FDA is actually regulating projects that are built by complex supply chains. It doesn't matter if it is a device, a therapeutic or food. On the other hand, the information it needs to regulate these products has to come from a supply chain. If you were to—and I did this exercise in my former role at the CDC. We asked individuals, do you know what information you need to have to perform a specific task. Even that elemental question is difficult for people to answer. So we are really in a different phase, if you will, a stage of industrialization and so we need to help the FDA and other agencies and the private sector to move and leverage technology more efficiently. Start with the question, what is our information supply chain, what do we need to know, where does the data come from, how do we stimulate the development in entities we don't own to develop that capability. Hospitals—a small hospital that doesn't have that much money, how do you stimulate them to buy an electronic health record and then

integrate these electronic health records? It is being worked on but it is very complex.

Mr. BURGESS. Let me ask you this, because you alluded just a moment ago to the 12- to 24-month time frame was woefully inadequate. Now, Mr. Stupak is saying that we need to hear back from this panel within 60 days. Are you going to be able to report to us favorably within 60 days developing this type of advanced network that we are going to have within our information technology structure?

Dr. NORDENBERG. Two things. I think it falls on the FDA to come back to us, thankfully, and secondly, the way I divided up this problem is twofold. One is intramural, so I believe that the FDA can assess its intramural technology deficiencies and that can be remediated expeditiously.

Mr. BURGESS. Let me just stop you there for a second. Have we not already done that with this panel, with this subcommittee, with this board? Was that not your job to identify those——

Dr. NORDENBERG. Our job was not to get down to the nitty-gritty level, for example, of identifying how many boxes need to be replaced and what software applications specifically might need to be replaced. Our job was, the way I understand it, is to evaluate what capability does the FDA have. So for example, if there is a system that exists to look at imports but you interview and you speak with people across the agency and senior levels of multiple centers and you say are you getting the data and information you need with regards to the imports, the importation of products that the FDA regulates, and they answer universally no, the best system in the world is moot. The information supply chain does not exist or it is broken. So——

Mr. BURGESS. That is your current assessment at the FDA now?

Dr. NORDENBERG. Our assessment, the subcommittee found that the information supply chains at the FDA are insufficient. The way it mentions the pre-market clinical trials, the post-market pharmacovigilance, the way data is flowing around imports, and this is not just a technology problem. This is a process problem. This is an information supply chain problem. When you look at the task at hand, they have to monitor what is going on at hundreds of thousands of sites be it manufacturing, warehousing, transportation.

Mr. BURGESS. No quarrel that it is a big job but again a few moments ago you said a 12- to 24-month time frame was unrealistic, way too much time to devote to that. What is the current amount of time? When should this subcommittee be able to come back to the FDA and have some assurance that at least we are on the right track as far as developing the right kind of information supply chain that you keep alluding to?

Dr. NORDENBERG. So let me try to answer that one more time. So if we look at what is inside the FDA and the environment that it controls, that could be remediated in months. Go assess what is deficient, buy the products, hire the people, whatever you need to do or dispatch your own people and remediate that. That is not solving the second issue that you are addressing, the large, complex, multi-stakeholder networks. That is not a couple of months fix. In fact, the country already is working on this at multiple lev-

els of the government. This gets back to the chairman's comment around, you know, what level should this be controlled. So HHS is already working from a healthcare perspective. It doesn't address—well, it probably doesn't address the animals as well. So from an overall healthcare perspective, as a chief enterprise architect, it has an office of health information technology but the FDA has specific—a specific mandate around assuring product safety and product efficacy for the products it regulates, and that longer-term challenge is much more complex that than shorter-term challenge that I mentioned, so you have to look at those two things entirely separately.

Mr. BURGESS. So can you give us estimates on what a reasonable time period is for the short-term challenge and the long-term challenge, what should——

Mr. STUPAK. I would ask you to answer that and that will have to be it. It has been 10 minutes now, Mike.

Dr. NORDENBERG. So the short-term challenge of assessing the intramural technology deficiencies and having a plan to mitigate that, that should easily be able to be done within 60 days.

Mr. BURGESS. And the longer-term challenge?

Dr. NORDENBERG. The longer-term challenge is—that will be—to develop a plan for that is closer probably to a 6-month effort. It is going to have to be a staged capability assessment. So what do they want to be able to do in 6 months, 12 months, 18 months, 24 months is much more complex. In fact, I believe it would require—and I believe the subcommittee has stated as such that it requires extramural collaborations both in terms of academia and the private sector to address that latter problem. Advisory groups have to be stood up, collaborations have to be established. It is not something the FDA can do alone.

Mr. HUTT. And there are no funds to do it.

Mr. BURGESS. We are going to get you the funds. Chairman Stupak has promised that. Are we going to become an appropriating committee, because that would just be a lot easier.

Mr. STUPAK. If you want to go the appropriations committee, that is fine with me.

I would go next to Mr. Melancon for questions, please.

Mr. MELANCON. Yes. My colleague was talking about I guess etiquette. After a number of hearings and a number of reports and allowing for the administrator to be the first person up, we still haven't gotten any answers, and here we are in 2008 and there is an article in the New York Times that the current agency would need at least 27 years to inspect every foreign medical device plant, 13 years to check every foreign drug plant, 1,900 years to examine every foreign food plant. You know, that is kind of disappointing to hear. And in reviewing generally the presentation that was going to be given by the administrator, I find it vague. So having this group up here to tell us what we need to be looking at, to understand what the problems are internally, whether it is political, financial or otherwise, I think it is about time that it got here because maybe now we can ask the question and hopefully the administrator can give us good, straight answers on those questions so that we can help him fix the problems within this agency. You know, it takes money, and when we are $9 trillion in projected defi-

cits, it is hard to fix much of anything. But at the same time, if we can't protect America, what are we here for?

I don't know that I have a whole lot of questions because what we are talking about, I think, and tell me if I am off base, we are going to have one-time items that are going to be pretty sizable across the board from the bottom up to get this thing back rolling and then we are going to have some numbers that are going to have to be projected out over the next couple of years so that we can rebuild the force, rebuild the technology and put all the infrastructure back in place to make this agency a viable agency. Is there any place in there, can you see any place where we can cooperate with USDA, with maybe NOAA or maybe anybody that is out there that has inspection capabilities to help us through this process or are we faced with agencies that will not cooperate with each other? Is that a problem anywhere?

Dr. WOTEKI. Well, I can respond from the food and veterinary medicine side, and yes, there are opportunities to leverage what FDA has, particularly with respect to inspection capabilities and FSIS and also with respect to outreach to the academic community that Dr. FitzGerald spoke about. Trying to get the NIH, for example, or the Agricultural Research Service as another example or the Cooperative State Research Education and Extension Service to focus on the regulatory science needs of the Food and Drug Administration would go a long way towards helping CFSAN and CVM to have the science base that they need to do their jobs. So how to get that leverage for FDA with the research agencies to address their problems and so that those research agencies in turn in the grants that they provide to the academic community will be shaping those grants so that they are focusing again on the regulatory science needs is the kind of leveraging that FDA needs. We do make a recommendation in the report that is in the section towards the back where the individual agency reports are that providing funds to FDA that they could actually then use to leverage with the research funding agencies, partnering in essence to fund this regulatory science agenda would go a long ways towards helping to rebuild that science base that they need.

Ms. CASSELL. I would also just point out that NASA many years ago began to develop methodologies to detect microbial contamination in the air-handling system and the water systems of the space shuttle. Then the Department of Defense and Homeland Security have capitalized on these and have invested millions and billions of dollars over the last few years in particular on improved systems for microbial sampling of food and water and in addition have invested heavily in information technology in terms of data mining and other capabilities as it relates to handling of large amounts of data, and it would seem that there would be ways that one could capitalize on that investment that has already been made and to leverage that. But as Dr. Woteki has said, I think with the agency, i.e., FDA having resources to bring to the table to help allow that leveraging and also the personnel internally to bring that leveraging back into the agency would be extremely important, and we do make these recommendations in the report, but you are absolutely right about leveraging. We have to do this.

Mr. MELANCON. I yield back my time.

Mr. STUPAK. Thank you.

Well, let me thank this panel once again. We could go on for a long time but we do have two more panels. I want to thank this Subcommittee of the Science Review Board and all the experts on the Science Review Board. For the last year you have given up many, many hours of your time and your expertise and you put in thousands of hours because you truly care about the FDA and improving and reforming the FDA as you indicated, and I think every member up here too, we have deep respect for the FDA but it is an issue that we feel needs attention, whether it is resources, whether it is—but your input is greatly appreciated and I hope the Commissioner would take your comments to heart and work with you and not just dismiss this panel and the expertise you bring to this issue because it truly for the benefit of the American people. Thank you, each and every one on this panel. You are excused. Thank you.

I would like to call our second panel of witnesses to come forward. On our second panel, we have Dr. Marcia Crosse, director of the public health and military healthcare issues at the U.S. Government Accountability Office, Miss Lisa Shames, director of food and agriculture issues at the U.S. Government Accountability Office, and Dr. Donna Porter, specialist in life science, Science Policy Research Division at the Congressional Research Service.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right under the rules of the House to be advised by counsel during their testimony. Do any of you wish to be represented by counsel? Everyone indicating—our witnesses indicate they do not. So I am going to ask you to please rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect the witnesses replied in the affirmative. You are now under oath. We will begin with a 5-minute opening statement. As I indicated in the last panel, if you have attachments, they will be submitted for the record with your full testimony, so if you want to summarize it, you have 5 minutes each.

Dr. Crosse, we will begin with you, please. Thank you.

STATEMENT OF MARCIA G. CROSSE, PH.D., DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Ms. CROSSE. Thank you, Mr. Chairman, members of the subcommittee. I am pleased to be here today as you examine FDA's capacity to carry out its mission.

I testified before this committee in November on FDA's program to inspect foreign manufacturers of pharmaceuticals for the U.S. market. At that time I discussed how FDA's programs were not keeping up with the globalization of drug manufacturing. I testified about FDA's infrequent inspections, weaknesses in its data systems and challenges unique to foreign inspections. You asked that we conduct a similar examination of FDA's medical device inspection program and our findings mirror the weaknesses that we found for drugs. GAO has also examined concerns regarding the safety of the food supply, on which my colleague will testify.

FDA is required by statute to inspect every 2 years all domestic establishments manufacturing medical devices classified as being of high risk, such as pacemakers and defibrillators, or medium risk, such as syringes and hearing aids. There is no comparable time requirement for inspecting foreign establishments but FDA is responsible for ensuring that they meet the same standards required of domestic establishments. Inspections of products at the border cannot substitute for onsite inspections to determine if products are manufactured under proper conditions.

We found that for medical devices, just as for drugs, FDA has not met the statutory requirement for domestic inspections. FDA inspects domestic establishments about every 3 years for high-risk devices or 5 years for medium-risk devices. Foreign medical device establishments are inspected less frequently, about every 6 years for high-risk devices or 27 years for medium-risk devices. As with drugs, China is the foreign country with the largest number of establishments registered to manufacture medical devices for the U.S. market and it is in China that the mismatch between the number of establishments and the number of inspections is the largest. Almost 700 Chinese device establishments are registered, and in the 6-year period that we examined, a total of 64 inspections were performed.

FDA faces particular challenges in managing its foreign inspection program. Two FDA databases contain inaccuracies that create very different estimates of the number of foreign medical device establishments subject to inspection. As we have heard today, these systems cannot exchange information, and any comparisons are done manually. In addition, inspections of foreign device establishments pose the same challenges to FDA in human resources and logistics as we found for drug inspections. FDA depends upon volunteer inspectors, has no independent translators, and has difficulty altering the travel itinerary if problems are uncovered that might warrant further review.

Over the years there has been interest in using third parties to supplement FDA's inspection resources. The Medical Device User Fee and Modernization Act of 2002 required FDA to accredit third parties to inspect certain establishments and FDA has implemented two such voluntary programs. These programs allow for a single inspection that can meet the requirements of FDA and of other countries, which serves as an incentive by allowing a company that markets its devices in many countries to reduce the number of inspections. Disincentives to using third-party inspectors include bearing the cost for the inspection and exposing the company to possible regulatory action. This last point is of particular note because hiring a third-party inspector ensures that an inspection will take place whereas it could be many years before FDA arrives for an inspection. We found that few inspections have been conducted through FDA's programs. In the 4 years since FDA first cleared an accredited organization to conduct independent medical device inspections, a total of seven inspections have been conducted.

In conclusion, our findings are consistent with the Science Board's findings regarding FDA's ability to fulfill its regulatory responsibilities. Our findings also support the Science Board's conclu-

sions that the agency's work is jeopardized by information technology and human resource challenges. In addition, the small number of inspections completed by accredited third parties has not assisted FDA in meeting its regulatory responsibilities. This raises questions about the ability of such third-party programs to quickly help FDA fulfill other responsibilities.

Mr. Chairman, this concludes my prepared remarks. I would be happy to answer any questions you or other members of the subcommittee may have.

[The prepared statement of Dr. Crosse follows:]

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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MEDICAL DEVICES

Challenges for FDA in Conducting Manufacturer Inspections

Statement of Marcia Crosse, Director
Health Care

GAO-08-428T

January 29, 2008

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Highlights

Highlights of GAO-08-428T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

MEDICAL DEVICES

Challenges for FDA in Conducting Manufacturer Inspections

Why GAO Did This Study

As part of the Food and Drug Administration's (FDA) oversight of the safety and effectiveness of medical devices marketed in the United States, it inspects domestic and foreign establishments where these devices are manufactured. To help FDA address shortcomings in its inspection program, the Medical Device User Fee and Modernization Act of 2002 required FDA to accredit third parties to inspect certain establishments. In response, FDA has implemented two such voluntary programs. GAO previously reported on the status of one of these programs, citing concerns regarding its implementation and factors that may influence manufacturers' participation. (Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations, GAO-07-157, January 2007.)

This statement (1) assesses FDA's management of inspections of establishments—particularly those in foreign countries—manufacturing devices for the U.S. market, and (2) provides the status of FDA's programs for third-party inspections of medical device manufacturing establishments. GAO interviewed FDA officials; reviewed pertinent statutes, regulations, guidance, and reports; and analyzed information from FDA databases. GAO also updated its previous work on FDA's programs for inspections by accredited third parties.

To view the full product, including the scope and methodology, click on GAO-08-428T. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

FDA has not met the statutory requirement to inspect certain domestic establishments manufacturing medical devices every 2 years, and the agency faces challenges inspecting foreign establishments. FDA primarily inspected establishments located in the United States. The agency has not met the biennial inspection requirement for domestic establishments manufacturing medical devices that FDA has classified as high risk, such as pacemakers, or medium risk, such as hearing aids. FDA officials estimated that the agency has inspected these establishments every 3 years (for high risk devices) or 5 years (for medium risk devices). There is no comparable requirement to inspect foreign establishments, and agency officials estimate that these establishments have been inspected every 6 years (for high risk devices) or 27 years (for medium risk devices). FDA faces challenges in managing its inspections of foreign medical device establishments. Two databases that provide FDA with information about foreign medical device establishments and the products they manufacture for the U.S. market contain inaccuracies that create disparate estimates of establishments subject to FDA inspection. Although comparing information from these two databases could help FDA determine the number of foreign establishments marketing medical devices in the United States, these databases cannot exchange information and any comparisons must be done manually. Finally, inspections of foreign medical device manufacturing establishments pose unique challenges to FDA in human resources and logistics.

Few inspections of medical device manufacturing establishments have been conducted through FDA's two accredited third-party inspection programs—the Accredited Persons Inspection Program and the Pilot Multi-purpose Audit Program (PMAP). From March 11, 2004—the date when FDA first cleared an accredited organization to conduct independent inspections—through January 11, 2008, five inspections have been conducted by accredited organizations through FDA's Accredited Persons Inspection Program. An incentive to participation in the program is the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements. Disincentives include bearing the cost for the inspection, particularly when the consequences of an inspection that otherwise might not occur in the near future could involve regulatory action. The Food and Drug Administration Amendments Act of 2007 made several changes to program eligibility requirements that could result in increased participation by manufacturers. PMAP was established on September 7, 2006, and as of January 11, 2008, two inspections had been conducted by an accredited organization through this program, which is more limited than the Accredited Persons Inspection Program. The small number of inspections completed to date by accredited third-party organizations raises questions about the practicality and effectiveness of establishing similar programs that rely on third parties to quickly help FDA fulfill its responsibilities.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you examine how the Food and Drug Administration (FDA) has been meeting its regulatory responsibilities. One area of FDA responsibility is the regulation of medical devices[1]—such as hearing aids and pacemakers—marketed in the United States, whether manufactured in domestic or foreign establishments.[2] FDA classifies medical devices into one of three classes based on degree of potential risk and level of control needed to reasonably ensure safety and effectiveness.[3] Inspection of establishments is FDA's primary means of assuring that the safety and effectiveness of medical devices are not jeopardized by poor manufacturing practices. Requirements governing domestic and foreign inspections differ. Specifically, FDA is required to inspect domestic establishments that manufacture class II (medium risk) or III (high risk) medical devices every 2 years.[4] There is no comparable requirement to inspect foreign establishments.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) addressed concerns about FDA's ability to meet its responsibilities for inspecting medical device manufacturing establishments.[5] MDUFMA included provisions designed to (1) increase the number of inspected medical device manufacturing establishments and (2) help manufacturers

[1]Medical devices include instruments, apparatuses, machines, and implants that are intended for use to diagnose, cure, treat, or prevent disease, or to affect the structure or any function of the body. 21 U.S.C. § 321(h).

[2]FDA regulations define an establishment as a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed. 21 C.F.R. § 807.3(c) (2007). Medical device manufacturers may have more than one establishment. We use the term "manufacture" to refer to activities including manufacturing, preparing, and processing devices.

[3]21 U.S.C. § 360c. Medical devices are classified into one of three classes. Class I includes "low risk" devices, such as tongue depressors, elastic bandages, and bedpans. Class II includes "medium risk" devices, such as syringes, hearing aids, and electrocardiograph machines. Class III includes "high risk" devices, such as heart valves, pacemakers, and defibrillators.

[4]21 U.S.C. § 360(h). There is no statutory requirement for inspection of class I medical device manufacturing establishments, and FDA does not routinely inspect them. However, FDA periodically inspects establishments manufacturing surgeon's gloves and patient examination gloves, which are both class I medical devices, due to ongoing problems with leakage. FDA also periodically inspects manufacturers of randomly selected class I devices.

[5]See Pub. L. No. 107-250, § 201, 116 Stat. 1588, 1602-09 (2002) (codified as amended at 21 U.S.C. § 374(g)).

meet the inspection requirements of both the United States and foreign countries in a single inspection. Specifically, MDUFMA required FDA to accredit third-party organizations to conduct inspections of certain domestic and foreign establishments.[6] In response, FDA implemented its Accredited Persons Inspection Program, which permits certain establishments to voluntarily request inspections from third-party organizations to meet inspectional requirements. In January 2007, we reported on the status of this program citing, among other things, concerns regarding its implementation and potential incentives and disincentives that may influence manufacturers' participation.[7] Additionally, in partnership with Health Canada,[8] FDA has established another program for inspection by accredited third parties—the Pilot Multi-purpose Audit Program (PMAP)—that allows accredited organizations to conduct a single inspection to meet the regulatory requirements of both countries. A report by the House of Representatives Committee on Energy and Commerce that accompanied MDUFMA stated that inspections by accredited third parties would permit FDA to focus the agency's inspection resources on manufacturers that have greater problems and devices that present higher risks.[9]

In addition to the questions about medical devices that led to the creation of FDA's third-party inspection program, questions have also been raised about how FDA is meeting its regulatory responsibilities in other program areas, such as drugs. In November 2007, we testified on our preliminary findings regarding FDA's program for inspecting foreign drug manufacturers.[10] Our findings suggested that FDA conducted infrequent inspections; had weaknesses in its data systems, including conflicting information on the number of foreign establishments; and faced challenges unique to foreign inspections, including those involving human resource issues. (See app. I for a summary of that testimony. We plan to

[6]In this report, unless otherwise noted, when we discuss inspections, we are referring to those conducted by FDA investigators.

[7]GAO, *Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations*, GAO-07-157 (Washington, D.C.: Jan. 5, 2007).

[8]Health Canada is the governmental entity that regulates medical devices marketed in Canada.

[9]H.R. Rep. No. 107-728, pt. 1, at 35-36 (2002).

[10]GAO, *Drug Safety: Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers*, GAO-08-224T (Washington, D.C.: Nov. 1, 2007).

issue a final report at a later date.) Also in November 2007, a subcommittee of the FDA Science Board[11] issued a report that identified growing demands on FDA, including the globalization of the industries that FDA regulates. The report found that disparities between FDA's responsibilities and its available resources—including human resources—have resulted in serious weaknesses that jeopardize the agency's ability to meet current and emerging regulatory responsibilities.[12] The subcommittee's report noted that these weaknesses include inadequate inspections of manufacturers. It also emphasized that FDA's information technology infrastructure is obsolete and unstable; provides an insufficient basis to access, integrate, and analyze data; and is subject to frequent system failures.

Third-party organizations have been identified as one mechanism that could help FDA address shortcomings in inspection programs, beyond the programs for medical devices. The federal Interagency Working Group on Import Safety recently suggested that the use of third-party organizations could provide FDA with information to help the agency target its inspection resources to those products of greatest risk.[13] In addition, we recommended that FDA consider developing a third-party inspection program to help it meet its responsibilities for inspecting foreign firms importing seafood to the United States.[14]

Given the recent questions regarding FDA's inspection programs and suggestions that third-party organizations could supplement FDA's resources, you asked for information on FDA's management of its medical device inspection program. My remarks will focus on (1) our assessment of FDA's program for inspecting establishments that manufacture medical

[11]The Science Board, which is an advisory board to the commissioner of FDA, provides advice on, among other things, specific complex and technical issues as well as emerging issues within the scientific community.

[12]FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (November 2007), http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html (accessed Jan. 18, 2008).

[13]In July 2007, the Interagency Working Group on Import Safety was established to conduct a comprehensive review of current import safety practices and determine where improvements could be made. Interagency Working Group on Import Safety, *Action Plan for Import Safety: A roadmap for continual improvement* (November 2007), http://www.importsafety.gov/report/actionplan.pdf (accessed Dec. 6, 2007).

[14]See GAO, *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements are Needed*, GAO-04-246 (Washington, D.C.: Jan. 30, 2004).

devices for the U.S. market, particularly those located in foreign countries and (2) the status of FDA's programs for third-party inspections of medical device manufacturing establishments. Today, in a separate statement, we are also discussing the federal oversight of food safety as a high-risk area and ways in which FDA can better leverage its resources.[15] These and other recent testimonies on drug safety and food safety offer some observations on FDA's inspection program capacity.

To address these issues, we interviewed officials from FDA's Center for Devices and Radiological Health (CDRH) and Office of Regulatory Affairs (ORA), which each have responsibilities for managing the medical device inspection program.[16] We reviewed pertinent statutes and regulations, as well as agency documents that provide guidance on FDA's inspection requirements and programs for inspections by accredited third parties. To assess FDA's program for inspecting establishments that manufacture medical devices, we obtained information from FDA's Device Registration and Listing System (DRLS), as of September 19, 2007; Field Accomplishments and Compliance Tracking System (FACTS) for fiscal year 2002 through fiscal year 2007; and Operational and Administrative System for Import Support (OASIS) for fiscal year 2007. We assessed the reliability of these data by (1) reviewing existing information about the data and the databases that produced them, (2) interviewing agency officials knowledgeable about the data, and (3) performing electronic testing of data elements from DRLS and FACTS. We found the data in the FACTS database sufficiently reliable for our purposes. We also found that DRLS was sufficiently reliable, to the extent that it accurately reflects information provided by domestic and foreign establishments that register to market medical devices in the United States. However, we determined that these data do not necessarily reflect the number of establishments that manufacture medical devices for the U.S. market. In addition, we found that OASIS is likely to overestimate the number of foreign establishments whose medical devices have been imported into the United States, due to uncorrected errors in the data. Therefore, we present

[15]GAO, *Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out is Critical*, GAO-08-435T (Washington, D.C.: Jan. 29, 2008).

[16]Within FDA, the Center for Biologics Evaluation and Research regulates medical devices involved in human immunodeficiency virus (HIV) testing and the collection, processing, testing, manufacture, and administration of licensed blood, blood components, and cellular products. We did not include medical devices regulated by this center in the scope of our work.

information from both DRLS and OASIS to illustrate the variability in information that FDA's databases provide to agency officials on this topic. These data represent the best information available and are what FDA relies on to manage its domestic and foreign medical device inspection activities.

To examine the status of FDA's programs for third-party inspections, we received FDA data on the number of inspections conducted by accredited third parties from March 11, 2004—the date when FDA first cleared an accredited organization to conduct inspections—through January 11, 2008. This updates the data we obtained for our January 2007 report for which data collection ended on October 31, 2006. We also obtained information from FDA about other critical aspects of their programs for inspections by accredited third parties, such as the number of accredited organizations. To gain perspective on recent changes to FDA's programs for inspections by accredited third parties, we contacted representatives of the same 13 affected entities we interviewed for our January 2007 report on this topic.[17] We received responses from 2 of 4 accredited organizations, 2 of 3 organizations that represent medical device manufacturers, and 1 of 6 manufacturers. We received technical comments on a draft of this statement from FDA, which we incorporated, as appropriate. We conducted this performance audit from December 2007 to January 2008, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In summary, we found that FDA has not met the requirement to inspect domestic establishments manufacturing class II or III medical devices every 2 years and faces challenges in inspecting foreign establishments. FDA primarily inspected domestic establishments. FDA officials estimated that the agency has inspected domestic class II manufacturers every 5 years and domestic class III manufacturers every 3 years. There is no comparable requirement to conduct foreign inspections and FDA has conducted relatively few. Officials estimated the agency has inspected foreign class II manufacturers every 27 years and foreign class III

[17]These affected entities included accredited organizations, organizations that represent medical device manufacturers, and medical device manufacturers.

manufacturers every 6 years. In addition, FDA faces challenges in managing its foreign medical device inspection program. Two databases that provide FDA with information about foreign medical device establishments and the products they manufacture for the U.S. market contain inaccuracies that create divergent estimates of establishments subject to FDA inspection. Despite the divergent estimates, FDA does not routinely verify these data. Although comparing information from these two databases could help FDA determine the number of foreign establishments marketing medical devices in the United States, these databases cannot exchange information and any comparisons must be done manually. While the agency has taken steps to improve these databases, it is too soon to know if these changes will improve FDA's data. Finally, inspections of foreign medical device manufacturing establishments pose unique challenges to FDA, such as difficulties in recruiting investigators to voluntarily travel to certain countries and in extending trips if problems are identified during inspections. Our results are consistent with our November 2007 testimony on FDA's foreign drug inspection program, as well as the findings of the FDA Science Board.

Few inspections of medical device manufacturing establishments have been conducted through FDA's two programs for inspections by accredited third parties—the Accredited Persons Inspection Program and PMAP. From March 11, 2004—the date when FDA first cleared an accredited organization to conduct inspections—through January 11, 2008, five inspections have been conducted by accredited organizations through FDA's Accredited Persons Inspection Program. Manufacturers' decisions to request an inspection by an accredited organization might be influenced by both potential incentives and disincentives. An incentive to participation in the program is the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements. Disincentives include bearing the cost for the inspection, particularly when the consequences of an inspection that otherwise may not occur in the near future could involve regulatory action. The Food and Drug Administration Amendments Act of 2007 (FDAAA) changed the requirements for inspections by accredited third parties in several ways, which could result in increased participation by manufacturers, although it is too soon to tell. For example, an eligibility requirement that foreign establishments be periodically inspected by FDA was eliminated. Device manufacturers may also request an inspection by an accredited third party through PMAP, which was established on September 7, 2006. As of January 11, 2008, two inspections had been conducted by an accredited organization through PMAP, which is more limited than the Accredited Persons Inspection Program. The small number of inspections completed

to date by accredited third-party organizations raises questions about the practicality and effectiveness of establishing similar programs that rely on third parties to help FDA fulfill other responsibilities.

Background

FDA is responsible for overseeing the safety and effectiveness of medical devices that are marketed in the United States, whether manufactured in domestic or foreign establishments. All establishments that manufacture medical devices for marketing in the United States must register with FDA.[18] As part of its efforts to ensure the safety, effectiveness, and quality of medical devices, FDA is responsible for inspecting certain domestic and foreign establishments to ensure that they meet manufacturing standards established in FDA's quality system regulation.[19] FDA does not have authority to require foreign establishments to allow the agency to inspect their facilities. However, FDA has the authority to prevent the importation of products manufactured at establishments that refuse to allow an FDA inspection.[20] Unlike food, for which FDA primarily relies on inspections at the border, physical inspection of manufacturing establishments is a critical mechanism in FDA's process to ensure that medical devices and drugs are safe and effective and that manufacturers adhere to good manufacturing practices.

Within FDA, CDRH assures the safety and effectiveness of medical devices. Among other things, CDRH works with ORA, which conducts inspections of both domestic and foreign establishments to ensure that devices are produced in conformance with federal statutes and regulations, including the quality system regulation. FDA may conduct inspections before and after medical devices are approved or otherwise cleared to be marketed in the United States.

- Premarket inspections are conducted before FDA will approve U.S. marketing of a new medical device that is not substantially equivalent to

[18]21 U.S.C. § 360(b), (i).

[19]21 C.F.R. pt. 820 (2007). The quality system regulation requires, among other things, that domestic or foreign manufacturers have a quality system in place to implement current good manufacturing practices in the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices intended for human use in the United States. A quality system includes the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

[20]See 21 U.S.C. § 381(a); 21 C.F.R. § 820.1(d) (2007).

one that is already on the market.[21] Premarket inspections primarily assess manufacturing facilities, methods, and controls and may verify pertinent records.

- Postmarket inspections are conducted after a medical device has been approved or otherwise cleared to be marketed in the United States and include several types of inspections: (1) Quality system inspections are conducted to assess compliance with applicable FDA regulations, including the quality system regulation to ensure good manufacturing practices and the regulation requiring reporting of adverse events.[22] These inspections may be comprehensive or abbreviated, which differ in the scope of inspectional activity. Comprehensive postmarket inspections assess multiple aspects of the manufacturer's quality system, including management controls, design controls, corrective and preventative actions, and production and process controls. Abbreviated postmarket inspections assess only some of these aspects, but always assess corrective and preventative actions. (2) For-cause and compliance follow-up inspections are initiated in response to specific information that raises questions or problems associated with a particular establishment. (3) Postmarket audit inspections are conducted within 8 to 12 months of a premarket application's approval to examine any changes in the design, manufacturing process, or quality assurance systems.

  FDA determines which establishments to inspect using a risk-based strategy. High priority inspections include premarket approval inspections for class III devices, for-cause inspections, inspections of establishments that have had a high frequency of device recalls, and other devices and manufacturers FDA considers high risk. The establishment's inspection history may also be considered. A provision in FDAAA may assist FDA in making decisions about which establishments to inspect because it authorizes the agency to accept voluntary submissions of audit reports addressing manufacturers' conformance with internationally established standards for the purpose of setting risk-based inspectional priorities.[23]

[21]Currently, most medical devices are cleared for marketing in the United States because they are "substantially equivalent" to a marketed device. FDA generally does not conduct premarket inspections of establishments manufacturing these types of medical devices.

[22]21 C.F.R. pt. 803 (2007).

[23]Pub. L. No. 110-85, § 228, 121 Stat. 858 (2007).

FDA's programs for domestic and foreign inspections by accredited third parties provide an alternative to the traditional FDA-conducted comprehensive postmarket quality system inspection for eligible manufacturers of class II and III medical devices. MDUFMA required FDA to accredit third persons—which are organizations—to conduct inspections of certain establishments. In describing this requirement, the House of Representatives Committee on Energy and Commerce noted that some manufacturers have faced an increase in the number of inspections required by foreign countries, and that the number of inspections could be reduced if the manufacturers could contract with a third-party organization to conduct a single inspection that would satisfy the requirements of both FDA and foreign countries.[24] Manufacturers that meet eligibility requirements may request a postmarket inspection by an FDA-accredited organization.[25] The eligibility criteria for requesting an inspection of an establishment by an accredited organization include that the manufacturer markets (or intends to market) a medical device in a foreign country and the establishment to be inspected must not have received warnings for significant deviations from compliance requirements on its last inspection.[26]

MDUFMA also established minimum requirements for organizations to be accredited to conduct third-party inspections, including protecting against financial conflicts of interest and ensuring the competence of the organization to conduct inspections. FDA developed a training program for inspectors from accredited organizations that involves both formal classroom training and completion of three joint training inspections with FDA. Each individual inspector from an accredited organization must

[24]H.R. Rep. No. 107-728, pt. 1, at 32-36 (2002). Some foreign countries have accredited, certified, or otherwise recognized organizations to conduct inspections. We use the term "single inspection" to mean a complete inspection that covers all requirements of two or more countries, without repeating those activities covered under more than one set of requirements. A complete inspection can be conducted during a single block of time or in multiple phases. Two or more separate inspection reports could be generated on the basis of that single inspection.

[25]Accredited organizations may conduct comprehensive postmarket quality system inspections, but not other types of inspections of establishments that FDA has the authority to conduct, such as premarket or for-cause inspections. FDA may conduct its own inspections of establishments even after inspection by an accredited organization.

[26]21 U.S.C. § 374(g). FDAAA eliminated certain previously established eligibility requirements. For example, it eliminated a limitation on the number of consecutive inspections allowed by an accredited organization and a limitation that foreign establishments must be inspected periodically by FDA.

complete all training requirements successfully before being cleared to conduct independent inspections. FDA relies on manufacturers to volunteer to host these joint inspections, which count as FDA postmarket quality system inspections.

A manufacturer that is cleared to have an inspection by an accredited third party enters an agreement with the approved accredited organization and schedules an inspection. Once the accredited organization completes its inspection, it prepares a report and submits it to FDA, which makes the final assessment of compliance with applicable requirements. FDAAA added a requirement that accredited organizations notify FDA of any withdrawal, suspension, restriction, or expiration of certificate of conformance with quality systems standards (such as those established by the International Organization for Standardization) for establishments they inspected for FDA.[27]

In addition to the Accredited Persons Inspection Program, FDA has a second program for accredited third-party inspections of medical device establishments. On September 7, 2006, FDA and Health Canada announced the establishment of PMAP. This pilot program was designed to allow qualified third-party organizations to perform a single inspection that would meet the regulatory requirements of both the United States and Canada. The third-party organizations eligible to conduct inspections through PMAP are those that FDA accredited for its Accredited Persons Inspection Program (and that completed all required training for that program) and that are also authorized to conduct inspections of medical device establishments for Health Canada. To be eligible to have a third-party inspection through PMAP, manufacturers must meet all criteria established for the Accredited Persons Inspection Program. As with the Accredited Persons Inspection Program, manufacturers must apply to participate and be willing to pay an accredited organization to conduct the inspection.

FDA relies on multiple databases to manage its program for inspecting medical device manufacturing establishments.

- DRLS contains information on domestic and foreign medical device establishments that have registered with FDA. Establishments that are involved in the manufacture of medical devices intended for commercial

[27]21 U.S.C. § 374(g)(3)(F).

distribution in the United States are required to register annually with FDA. These establishments provide information to FDA, such as establishment name and address and the medical devices they manufacture. As of October 1, 2007, establishments are required to register electronically through FDA's Unified Registration and Listing System and certain medical device establishments pay an annual establishment registration fee, which in fiscal year 2008 is $1,706.[28]

- OASIS contains information on medical devices and other FDA-regulated products imported into the United States, including information on the establishment that manufactured the medical device. The information in OASIS is automatically generated from data managed by U.S. Customs and Border Protection, which are originally entered by customs brokers based on the information available from the importer.[29]

- FACTS contains information on FDA's inspections, including those of domestic and foreign medical device establishments. FDA investigators enter information into FACTS following completion of an inspection.

According to FDA data, more than 23,600 establishments that manufacture medical devices were registered as of September 2007, of which 10,600 reported that they manufacture class II or III medical devices.[30] More than half—about 5,600—of these establishments were located in the United States. As of September 2007, there were more registered establishments in China and Germany reporting that they manufacture class II or III medical devices than in any other foreign countries.[31] Canada, Taiwan, and the United Kingdom also had a large number of registered establishments. (See fig. 1.) Registered foreign establishments reported that they manufacture a variety of class II and III medical devices for the U.S.

[28]21 U.S.C. § 379j(a)(3), (b).

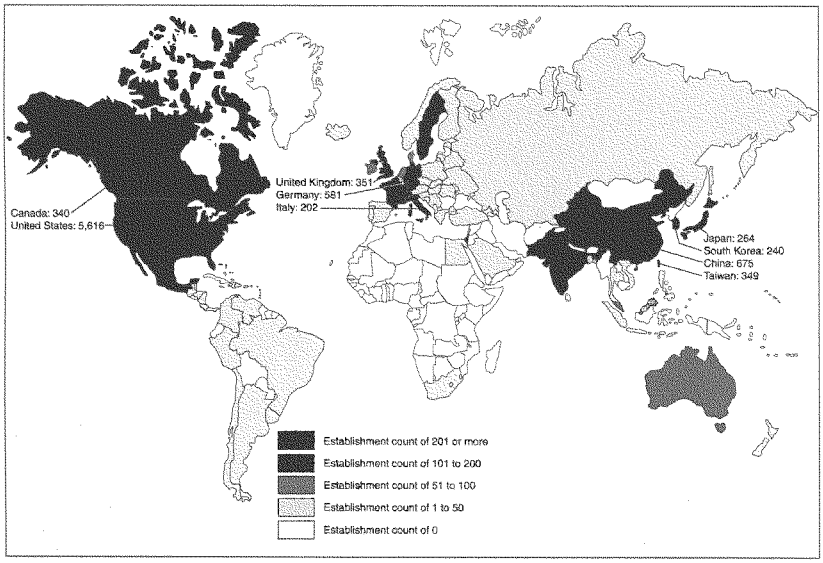
[29]Customs brokers are private individuals, partnerships, associations, or corporations licensed, regulated, and empowered by U.S. Customs and Border Protection to assist in meeting federal requirements governing imports and exports.

[30]Throughout this testimony, we use DRLS data because FDA officials told us that the agency would continue to use those data, as available on September 19, 2007, until it is confident that all device establishments required to register have done so through the new electronic system, FDA's Unified Registration and Listing System.

[31]Counts of registered establishments in China do not include establishments registered in Hong Kong or Taiwan as these establishments are tracked separately in DRLS.

market. For example, common class III medical devices included coronary stents,[32] pacemakers, and contact lenses.

Figure 1: Registered Establishments That Reported Manufacturing Class II or Class III Medical Devices for the U.S. Market, by Country, September 2007



Source: GAO analysis of FDA data.

Note: Counts of registered establishments in China do not include establishments registered in Hong Kong or Taiwan as these establishments are tracked separately in DRLS. In addition, DRLS contained one additional registered establishment for which location information was not available.

[32]A coronary stent is a small tube that is placed within a coronary artery to keep the vessel open.

FDA Is Not Inspecting Domestic Establishments Biennially as Required and Faces Challenges in Inspecting Foreign Establishments

FDA has not met the statutory requirement to inspect domestic establishments manufacturing class II or III medical devices every 2 years. The agency conducted relatively few inspections of foreign establishments. The databases that provide FDA with data about the number of foreign establishments manufacturing medical devices for the U.S. market contain inaccuracies. In addition, inspections of foreign medical device manufacturing establishments pose unique challenges to FDA—both in human resources and logistics.

FDA Is Not Inspecting Domestic Establishments Biennially and Inspects Relatively Few Foreign Establishments

From fiscal year 2002 through fiscal year 2007, FDA primarily inspected establishments located in the United States, where more than half of the 10,600 registered establishments that reported manufacturing class II or III medical devices are located. In contrast, FDA inspected relatively few foreign medical device establishments. During this period, FDA conducted an average of 1,494 domestic and 247 foreign establishment inspections each year.[32] This suggests that each year FDA inspects about 27 percent of registered domestic establishments that reported manufacturing class II or class III medical devices and about 5 percent of such foreign establishments. The inspected establishments were in the United States and 44 foreign countries. Of the foreign inspections, more than two-thirds were in 10 countries. Most of the countries with the highest number of inspections were also among those with the largest number of registered establishments that reported manufacturing class II or III medical devices. The lowest rate of inspections in these 10 countries was in China, where 64 inspections were conducted in this 6-year period and almost 700 establishments were registered. (See table 1.)

[32]We were unable to differentiate inspections according to medical device classification. FDA's inspection database contains the most recent information available to FDA about the class of device manufactured at the establishment, and consequently does not contain readily available information about the class of devices manufactured at the time of a specific inspection. As a result, the data we present include all inspections, regardless of the classification of the manufactured device or devices. According to FDA officials, FDA primarily conducts inspections of establishments manufacturing class II or III medical devices.

Table 1: Number of FDA Inspections of Medical Device Establishments, Fiscal Year 2002 through Fiscal Year 2007

	Number of inspections[a]							
Country	FY2002	FY2003	FY2004	FY2005	FY2006	FY2007	Total	Number of registered class II or III manufacturing establishments[b]
United States	1,261	1,736	1,631	1,471	1,501	1,362	**8,962**[c]	5,616
Germany	39	30	34	51	25	52	**231**	581
United Kingdom	25	31	28	14	25	43	**166**	351
Canada	17	17	24	11	13	26	**108**	340
Japan	7	8	20	21	16	25	**97**	264
Ireland	15	22	13	13	16	11	**90**	67
France	16	14	17	14	12	10	**83**	190
Switzerland	6	12	19	9	7	18	**71**	134
China[d]	0	0	21	19	11	13	**64**	675[e]
Mexico	10	7	12	8	12	11	**60**	143
Italy	8	7	10	6	13	11	**55**	202
All other countries	66	83	102	67	69	69	**456**	2,036
Total	**1,470**	**1,967**	**1,931**	**1,704**	**1,720**	**1,651**	**10,443**	**10,600**[f]

Source: GAO analysis of FDA data.

[a]We were unable to differentiate inspections according to medical device classification. FDA's inspection database contains the most recent information available to FDA about the class of device manufactured at the establishment, and consequently does not contain readily available information about the class of devices manufactured at the time of a specific inspection. As a result, the data we present include all inspections, regardless of the classification of the manufactured device or devices. According to FDA officials, FDA primarily conducts inspections of establishments manufacturing class II or III medical devices.

[b]These counts represent the number of registered establishments as of September 2007.

[c]In addition to inspections conducted by FDA personnel, from fiscal year 2002 through fiscal year 2007, FDA contracted with states to conduct 164 quality system inspections. These inspections are not included in the total.

[d]The inspection counts for China do not include inspections conducted in Hong Kong or Taiwan as these inspections are tracked separately in FACTS.

[e]Counts of registered establishments in China do not include establishments registered in Hong Kong or Taiwan as these establishments are tracked separately in DRLS.

[f]Registration numbers do not add to total because DRLS contained one additional registered establishment for which location information was not available.

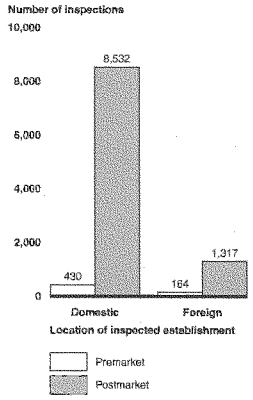
Despite its focus on domestic inspections, FDA has not met the statutory requirement to inspect domestic establishments manufacturing class II or III medical devices every 2 years. For domestic establishments, FDA officials estimated that, on average, the agency inspects class II

manufacturers every 5 years and class III manufacturers every 3 years. For foreign establishments—for which there is no comparable inspection requirement—FDA officials estimated that the agency inspects class II manufacturers every 27 years and class III manufacturers every 6 years.

FDA's inspections of medical device establishments, both domestic and foreign, are primarily postmarket inspections. While premarket inspections are generally FDA's highest priority, relatively few have to be performed in any given year.[34] Therefore, FDA focuses its resources on postmarket inspections. From fiscal year 2002 through fiscal year 2007, 95 percent of the 8,962 domestic establishment inspections and 89 percent of the 1,481 foreign establishment inspections were for postmarket purposes. (See fig. 2.)

[34]Currently, most medical devices are cleared for marketing in the United States because they are "substantially equivalent" to a marketed device. FDA generally does not conduct premarket inspections of establishments manufacturing these types of medical devices.

Figure 2: Number of Inspections of Domestic and Foreign Establishments That Manufacture Medical Devices for the U.S. Market, by Type of Inspection, Fiscal Year 2002 through Fiscal Year 2007



Source: GAO analysis of FDA data.

Note: If an inspection had both premarket and postmarket components, we classified it as a premarket inspection. Of the 430 domestic premarket inspections, 256 contained both premarket and postmarket components. Of the 164 foreign premarket inspections, 95 contained both premarket and postmarket components. FDA may conduct other types of inspections—such as a postmarket quality system, compliance follow-up, for-cause, or postmarket audit inspection—at the same establishment at which they are conducting a premarket inspection. These inspections may focus on different products manufactured at the same establishment.

FDA's Databases Provide Inconsistent Information Regarding the Number of Foreign Medical Device Manufacturing Establishments Subject to Inspection

FDA's databases on registration and imported products provide divergent estimates regarding the number of foreign medical device manufacturing establishments. DRLS provides FDA with information about domestic and foreign medical device establishments and the products they manufacture for the U.S. market. According to DRLS, as of September 2007, 5,616 domestic and 4,983 foreign establishments that reported manufacturing a class II or III medical device for the U.S. market had registered with FDA.[35] However, these data contain inaccuracies because establishments may register with FDA but not actually manufacture a medical device or may manufacture a medical device that is not marketed in the United States. FDA officials told us that their more frequent inspections of domestic establishments allow them to more easily update information about whether a domestic establishment is subject to inspection.

In addition to DRLS, FDA obtains information on foreign establishments from OASIS, which tracks the import of medical devices. While not intended to provide a count of establishments, OASIS does contain information about the medical devices actually being imported into the United States and the establishments manufacturing them. However, inaccuracies in OASIS prevent FDA from using it to develop a list of establishments subject to inspection. OASIS contains duplicate records for a single establishment because of inaccurate data entry by customs brokers at the border. According to OASIS, in fiscal year 2007, there were as many as 22,008 foreign establishments that manufactured class II medical devices for the U.S. market and 3,575 foreign establishments that manufactured class III medical devices for the U.S. market.[36] Despite the divergent estimates of foreign establishments generated by DRLS and OASIS, FDA does not routinely verify the data within each database. Although comparing information from these two databases could help FDA determine the number of foreign establishments marketing medical devices in the United States, the databases cannot exchange information to be compared electronically and any comparisons are done manually.

Efforts are underway that could improve FDA's databases. FDA officials suggested that, because manufacturers are now required to pay an annual establishment registration fee, manufacturers may be more concerned

[35]DRLS contained one additional registered establishment for which location information was not available.

[36]According to FDA officials, a single establishment could be manufacturing more than one class of device.

about the accuracy of the registration data they submit. They also told us that, because of the registration fee, manufacturers may be less likely to register if they do not actually manufacture a medical device for the U.S. market. In addition, FDA officials stated that the agency is pursuing various initiatives to try to address the inaccuracies in OASIS, such as providing a unique identifier for each foreign establishment to reduce duplicate entries for individual establishments.

Challenges Unique to Foreign Inspections Influence the Manner in Which FDA Conducts Such Inspections

Inspections of foreign establishments pose unique challenges to FDA—both in human resources and logistics. FDA does not have a dedicated cadre of investigators that only conduct foreign medical device establishment inspections; those staff who inspect foreign establishments also inspect domestic establishments. Among those qualified to inspect foreign establishments,[37] FDA relies on staff to volunteer to conduct inspections. FDA officials told us that it is difficult to recruit investigators to voluntarily travel to certain countries. However, they added that if the agency could not find an individual to volunteer for a foreign inspection trip, it would mandate the travel. Logistically, foreign medical device establishment inspections are difficult to extend even if problems are identified because the trips are scheduled in advance.[38] Foreign medical device establishment inspections are also logistically challenging because investigators do not receive independent translational support from FDA or the State Department and may rely on English-speaking employees of the inspected establishment or the establishment's U.S. agent to translate during an inspection.

[37]Staff members must meet certain criteria in terms of their experience and training to conduct inspections of foreign establishments. For example, they are required to take certain training courses and have at least 3 years of experience conducting domestic inspections before they can be considered qualified to conduct a foreign inspection.

[38]Typically, FDA investigators travel abroad for about 3 weeks at a time, during which they inspect approximately three establishments.

Few Third-Party Inspections Are Conducted, but Recent Changes Could Eliminate Some Obstacles to Manufacturers' Participation

Few inspections of medical device manufacturing establishments have been conducted through FDA's two accredited third-party inspection programs—the Accredited Persons Inspection Program and PMAP. FDAAA specified several changes to the requirements for inspections by accredited third parties that could result in increased participation by manufacturers.

Few inspections have been conducted through FDA's Accredited Persons Inspection Program since March 11, 2004—the date when FDA first cleared an accredited organization to conduct independent inspections. Through January 11, 2008, five inspections had been conducted independently by accredited organizations (two inspections of domestic establishments and three inspections of foreign establishments), an increase of three since we reported on this program one year ago.[39]

As of January 11, 2008, 16 third-party organizations were accredited,[40] and individuals from 8 of these organizations had completed FDA's training requirements and been cleared to conduct independent inspections.[41] As of January 8, 2008, FDA and accredited organizations had conducted 44 joint training inspections.[42] Fewer manufacturers volunteered to host training inspections than have been needed for all of the accredited organizations

[39]In January 2007, we reported that two inspections had been independently conducted by accredited organizations through the Accredited Persons Inspection Program—one inspection of a domestic establishment and one inspection of a foreign establishment. GAO-07-157, 11.

[40]FDA officials told us that no additional organizations have applied for accreditation since we issued our January 2007 report.

[41]In January 2007, we reported that 7 of the 16 accredited organizations had been cleared to conduct independent inspections. GAO-07-157, 11. One additional accredited organization was cleared to conduct independent inspections on October 18, 2007. Specific foreign jurisdictions that have certified, accredited, or otherwise recognized one or more of the FDA-accredited organizations that have been cleared to conduct independent inspections include all member states of the European Community, Australia, Canada, New Zealand, Norway, Taiwan, and the United Kingdom. Of the 8 third-party organizations that have been cleared to conduct independent inspections through the Accredited Persons Inspection Program, 4 may conduct inspections through PMAP.

[42]In January 2007, we reported that FDA and accredited organizations had conducted 37 joint training inspections. GAO-07-157, 11.

to complete their training.[43] Moreover, scheduling these joint training inspections has been difficult. FDA officials told us that, when appropriate, staff are instructed to ask manufacturers to host a joint training inspection at the time they notify the manufacturers of a pending inspection. FDA schedules inspections a relatively short time prior to an actual inspection,[44] and as we reported in January 2007, some accredited organizations have not been able to participate because they had prior commitments.

As we reported in January 2007, manufacturers' decisions to request an inspection by an accredited organization might be influenced by both potential incentives and disincentives. According to FDA officials and representatives of affected entities, potential incentives to participation include the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements. For example, one inspection conducted by an accredited organization was a single inspection designed to meet the requirements of FDA, the European Union, and Canada. Another potential incentive mentioned by FDA officials and representatives of affected entities is the opportunity to control the scheduling of the inspection by an accredited organization by working with the accredited organization. FDA officials and representatives of affected entities also mentioned potential disincentives to having an inspection by an accredited organization. These potential disincentives include bearing the cost for the inspection,[45] doubts about whether accredited organizations can cover multiple requirements in a single

[43]As we reported in January 2007, some representatives of affected entities speculated that manufacturers might not have volunteered to host training inspections because they believed that training inspections would require more time and effort for their staff (and would thus be more disruptive) than inspections conducted by fully trained personnel, or that manufacturers might have believed that training inspections would be more rigorous than nontraining inspections if the trainees and FDA personnel were to take particular care to demonstrate their thoroughness to each other.

[44]FDA generally notifies manufacturers about a week in advance of postmarket quality system inspections of domestic establishments and about 6 to 8 weeks in advance of postmarket quality system inspections of foreign establishments.

[45]In January 2007, we reported that representatives of accredited organizations indicated that the cost to manufacturers would vary depending on such factors as the size of the manufacturer and how much extra time would be required to assess compliance with FDA requirements. Representatives suggested that covering FDA's requirements could take 2 or more days in addition to the time spent assessing other countries' requirements, plus time for advance preparation and writing the inspection report. They speculated that they would probably charge manufacturers from $1,700 to $2,500 per day, plus the cost of travel and living expenses.

inspection, and uncertainty about the potential consequences of an inspection that otherwise may not occur in the near future—consequences that could involve regulatory action.

Changes specified by FDAAA have the potential to eliminate certain obstacles to manufacturers' participation in FDA's programs for inspections by accredited third parties that were associated with manufacturers' eligibility. For example, an eligibility requirement that foreign establishments be periodically inspected by FDA was eliminated. Representatives of the two organizations that represent medical device manufacturers with whom we spoke about FDAAA told us that the changes in eligibility requirements could eliminate certain obstacles and therefore potentially increase their participation. These representatives also noted that key incentives and disincentives to manufacturers' participation remain. FDA officials told us that they are currently revising their guidance to industry in light of FDAAA and expect to issue the revised guidance during fiscal year 2008. It is too soon to tell what impact these changes will have on manufacturers' participation.

FDA officials acknowledged that manufacturers' participation in the Accredited Persons Inspection Program has been limited. In December 2007, FDA established a working group to assess the successes and failures of this program and to identify ways to increase participation. Representatives of the two organizations that represent medical device manufacturers with whom we recently spoke stated that they believe manufacturers remain interested in the Accredited Persons Inspection Program. The representative of one large, global manufacturer of medical devices told us that it is in the process of arranging to have 20 of its domestic and foreign device manufacturing establishments inspected by accredited third parties.

As of January 11, 2008, two inspections, both of domestic establishments, had been conducted through PMAP, FDA's second program for inspections by accredited third parties. Although it is too soon to tell what the benefits of PMAP will be, the program is more limited than the Accredited Persons Inspection Program and may pose additional disincentives to participation by both manufacturers and accredited organizations. Specifically, inspections through PMAP would be designed to meet the requirements of the United States and Canada, whereas inspections conducted through the Accredited Persons Inspection Program could be designed to meet the requirements of other countries. In addition, two of the five representatives of affected entities noted that in contrast to inspections conducted through the Accredited Persons

Inspection Program, inspections conducted through PMAP could undergo additional review by Health Canada. Health Canada will review inspection reports submitted through this pilot program to ensure they meet its standards. This extra review poses a greater risk of unexpected outcomes for the manufacturer and the accredited organization, which could be a disincentive to participation in PMAP that is not present with the Accredited Persons Inspection Program.

Concluding Observations

Americans depend on FDA to ensure the safety and effectiveness of medical products, including medical devices, manufactured throughout the world. However, our findings regarding inspections of medical device manufacturers indicate weaknesses that mirror those presented in our November 2007 testimony regarding inspections of foreign drug manufacturers. In addition, they are consistent with the FDA Science Board's findings that FDA's ability to fulfill its regulatory responsibilities is jeopardized, in part, by information technology and human resources challenges. We recognize that FDA has expressed the intention to improve its data management, but it is too early to tell whether the intended changes will ultimately enhance the agency's ability to manage its inspection programs. We and others have suggested that the use of accredited third parties could improve FDA's ability to meet its inspection responsibilities. However, the implementation of its programs for inspecting medical device manufacturers has resulted in little progress. To date, its programs for inspections by accredited third parties have not assisted FDA in meeting its regulatory responsibilities nor have they provided a rapid or substantial increase in the number of inspections performed by these organizations, as originally intended. Although recent statutory changes to the requirements for inspections by accredited third parties may encourage greater participation in these programs, the lack of meaningful progress raises questions about the practicality and effectiveness of establishing similar programs that rely on third parties to quickly help FDA fulfill other responsibilities.

Mr. Chairman, this completes my prepared statement, I would be happy to respond to any questions you or the other Members of the subcommittee may have at this time.

Contacts and Acknowledgments

For further information about this testimony, please contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may found on the last page of this testimony. Geraldine Redican-Bigott, Assistant Director; Kristen Joan Anderson; Katherine Clark; Robert Copeland; William Hadley; Cathy Hamann; Mollie Hertel; Julian Klazkin; Lisa Motley; Daniel Ries; and Suzanne Worth made key contributions to this testimony.

Appendix I: Summary of GAO Testimony on FDA's Program for Inspecting Foreign Drug Manufacturers

In congressional testimony in November 2007, we presented our preliminary findings on the Food and Drug Administration's (FDA) program for inspecting foreign drug manufacturers.[1] We found that (1) FDA's effectiveness in managing the foreign drug inspection program continued to be hindered by weaknesses in its databases; (2) FDA inspected relatively few foreign establishments; and (3) the foreign inspection process involved unique circumstances that were not encountered domestically.

Our preliminary findings indicated that more than 9 years after we issued our last report on FDA's foreign drug inspection program,[2] FDA's effectiveness in managing this program continued to be hindered by weaknesses in its databases. FDA did not know how many foreign establishments were subject to inspection. Instead of maintaining a list of such establishments, FDA relied on information from several databases that were not designed for this purpose. One of these databases contained information on foreign establishments that had registered to market drugs in the United States, while another contained information on drugs imported into the United States. One database indicated about 3,000 foreign establishments could have been subject to inspection in fiscal year 2007, while another indicated that about 6,800 foreign establishments could have been subject to inspection in tbat year. Despite the divergent estimates of foreign establishments subject to inspection generated by these two databases, FDA did not verify the data within each database. For example, the agency did not routinely confirm that a registered establishment actually manufactured a drug for the U.S. market. However, FDA used these data to generate a list of 3,249 foreign establishments from which it prioritized establishments for inspection.

Because FDA was not certain how many foreign drug establishments were actually subject to inspection, the percentage of such establishments that had been inspected could not be calculated with certainty. We found that FDA inspected relatively few foreign drug establishments, as shown in table 2. Using the list of 3,249 foreign drug establishments from which FDA prioritized establishments for inspection, we found that the agency may inspect about 7 percent of foreign drug establishments in a given year. At

[1]GAO, *Drug Safety: Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers*, GAO-08-224T (Washington, D.C.: Nov. 1, 2007).

[2]GAO, *Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program*, GAO/HEHS-98-21 (Washington, D.C.: Mar. 17, 1998).

this rate, it would take FDA more than 13 years to inspect each foreign drug establishment on this list once, assuming that no additional establishments are subject to inspection.

Table 2: Number of FDA Inspections of Foreign Establishments Involved in the Manufacture of Drugs for the U.S. Market, Fiscal Year 2002 through Fiscal Year 2007

	Number of inspections							
Country	FY2002	FY2003	FY2004	FY2005	FY2006	FY2007[a]	Total	Number of establishments[b]
India	11	19	38	33	34	65	**200**	410
Germany	24	15	35	25	19	22	**140**	199
Italy	17	30	26	21	18	19	**131**	150
Canada	29	12	17	23	23	19	**123**	288
United Kingdom	19	22	15	18	15	13	**102**	169
France	14	15	13	12	16	24	**94**	162
China	11	9	17	21	17	13	**88**	714
Japan	11	13	14	21	13	15	**87**	196
Switzerland	12	12	11	17	9	14	**75**	83
Ireland	11	5	11	14	3	11	**55**	61
All other countries	63	38	63	61	45	80	**350**	817
Total	**222**	**190**	**260**	**266**	**212**	**295**	**1,445**	**3,249**

Source: GAO analysis of FDA data.

[a]Inspection data for fiscal year 2007 may not be complete because FDA provided these data as of September 26, 2007, prior to the end of the fiscal year.

[b]This count represents the number of establishments FDA used to plan its fiscal year 2007 prioritized surveillance inspections.

FDA's data indicated that some foreign drug manufacturers had not received an inspection, but FDA could not provide the exact number of foreign drug establishments that had never been inspected. Most of the foreign drug inspections were conducted as part of processing a new drug application or an abbreviated new drug application,[3] rather than as current good manufacturing practices (GMP) surveillance inspections, which are used to monitor the quality of marketed drugs. FDA used a risk-based

[3]FDA must approve a new drug application before a new drug product may be marketed in the United States; approval for a generic drug is sought through an abbreviated new drug application. FDA also reviews scientific and clinical data contained in the applications, as part of its process in considering them for approval to be marketed.

process, based in part on data from its registration and import databases, to develop a prioritized list of foreign drug establishments for GMP surveillance inspections in fiscal year 2007. According to FDA, about 30 such inspections were completed in fiscal year 2007, and at least 50 were targeted for inspection in fiscal year 2008. Further, inaccuracies in the data on which this risk-based process depended limited its effectiveness.

Finally, the very nature of the foreign drug inspection process involved unique circumstances that were not encountered domestically. For example, FDA did not have a dedicated staff to conduct foreign drug inspections and relied on those inspecting domestic establishments to volunteer for foreign inspections. While FDA may conduct unannounced GMP inspections of domestic establishments, it did not arrive unannounced at foreign establishments. It also lacked the flexibility to easily extend foreign inspections if problems were encountered due to the need to adhere to an itinerary that typically involved multiple inspections in the same country. Finally, language barriers can make foreign inspections more difficult to conduct than domestic ones. FDA did not generally provide translators to its inspection teams. Instead, they may have had to rely on an English-speaking representative of the foreign establishment being inspected, rather than an independent translator.

Mr. STUPAK. Thank you, Dr. Crosse.
Ms. Shames, opening statement, please.

STATEMENT OF LISA SHAMES, DIRECTOR, FOOD AND AGRICULTURE ISSUES, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Ms. SHAMES. Chairman Stupak and members of the subcommittee, I am pleased to be here today to discuss FDA's resources to meet its responsibilities for food safety.

There have been dramatic changes in the volume and variety of foods FDA regulates. Further, changing demographics and consumption patterns underscore the urgency for effective FDA oversight. More of the population is and increasingly will be susceptible to a foodborne illness. In addition, we are eating more foods that are often associated with foodborne illness such as leafy greens.

Today I will focus on three topics: GAO's designation of the Federal oversight of food safety as a high-risk area, opportunities to leverage resources in FDA's Food Protection Plan that was released last November, and tools that can help agencies address management challenges.

First, regarding food safety, FDA is one of 15 agencies that collectively administer over 30 laws addressing food safety. This fragmentation, as been noted earlier, calls into question whether the government can promote the integrity of the food supply. It is a key reason GAO added the Federal oversight of food safety to its high-risk list and cited the need for a government-wide reexamination of the system. For many years we have reported on problems with the food safety system including inconsistent oversight, ineffective coordination and the inefficient use of resources. One such problem worth nothing today is the mismatch between the government's resources for food safety and agencies' responsibilities. That is, as been noted, FDA regulates about 80 percent of the food supply but receives about 20 percent of food inspection resources. To help the government as a whole, we have recommended enacting comprehensive and risk-based legislation and reconvening a council on food safety. Further, with pressing fiscal challenges, a government-wide plan can help Congress balance trade-offs when resource allocations are made.

Second, FDA released its Food Protection Plan. This plan proposes several positive first steps that are intended to enhance food safety. GAO has recommended many of these proposals over the last few years such as opportunities for FDA to better leverage its resources, which is especially important for FDA's food safety responsibilities. Unlike FDA's programs for drugs and medical devices, FDA is not authorized to charge user fees for its food safety activities. Some of our recommendations are for FDA to establish equivalence agreements with other countries, certify third parties and accredit private labs for testing food.

We also found that FDA's food safety activities overlap with, if not duplicate, other agencies' activities. To use resources more efficiently, FDA could, for example, authorize the Department of Agriculture to inspect jointly regulated food processing plants and conduct joint inspector training programs with USDA.

It is also important to note that FDA plans to request the authority to order a food recall. As you know from the hearing your subcommittee held last spring, food recalls are voluntary. Federal agencies including FDA have no authority to compel companies to recall contaminated foods except for infant formula. In contrast, FDA has authority to recall unsafe biological products and medical devices. Other agencies that regulate the safety of products such as toys and tires have recall authority and have had to use it when companies did not cooperate.

While the Food Protection Plan proposes these positive first steps, more-specific information about the resources and strategies to implement the plan would facilitate oversight. FDA officials told us resource information would be released during the budget process. We were also told that implementation plans detail timelines, actions and deliverables. FDA officials do not intend to release these implementation plans but will keep the public informed of their progress. Nevertheless, without more information, it will be difficult for Congress and others to assess the likelihood of a plan's success.

Lastly, the Science Board cites numerous management challenges that have contributed to FDA's inability to fulfill its mission. GAO has identified some tools that agencies can use to address their management challenges. For example, a chief operating officer can elevate, integrate and institutionalize responsibilities to address these challenges. FDA recently spelled out the responsibilities for such a position. GAO has found that a performance agreement can promote further accountability. In addition, a well-designed commission along the lines of the Science Board can produce specific, practical recommendations that Congress can enact.

In conclusion, it is imperative that FDA is able to help ensure the safety of the Nation's food supply in the most efficient, effective, accountable and sustainable way. To do so, leveraging resources and building capacity will be critical.

This concludes my statement, and I would be pleased to answer any questions.

[The prepared statement of Ms. Shames follows:]

United States Government Accountability Office

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Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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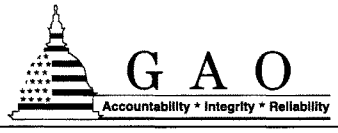
FEDERAL OVERSIGHT OF FOOD SAFETY

FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical

Statement of Lisa Shames, Director
Natural Resources and Environment



GAO-08-435T

January 29, 2008

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Highlights

Highlights of GAO-08-435T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

FEDERAL OVERSIGHT OF FOOD SAFETY

FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical

Why GAO Did This Study

The Food and Drug Administration (FDA) is responsible for ensuring the safety of roughly 80 percent of the U.S. food supply, including $417 billion worth of domestic food and $49 billion in imported food annually. The recent outbreaks of *E. coli* in spinach, *Salmonella* in peanut butter, and contamination in pet food highlight the risks posed by the accidental contamination of FDA-regulated food products. Changing demographics and consumption patterns underscore the urgency for effective food safety oversight. In response to these challenges, in November 2007, FDA and others released plans that discuss the oversight of food safety. FDA's *Food Protection Plan* sets a framework for food safety oversight. In addition, FDA's Science Board released *FDA Science and Mission at Risk*, which concluded that FDA does not have the capacity to ensure the safety of the nation's food supply.

This testimony focuses on (1) federal oversight of food safety as a high-risk area that needs a governmentwide reexamination, (2) FDA's opportunities to better leverage its resources, (3) FDA's *Food Protection Plan*, and (4) tools that can help agencies to address management challenges. To address these issues, GAO interviewed FDA officials; evaluated the *Food Protection Plan* using a GAO guide for assessing agencies' performance plans; and reviewed pertinent statutes and reports. GAO also analyzed data on FDA inspections and resources.

To view the full product, including the scope and methodology, click on GAO-08-435T. For more information, contact Lisa Shames at (202) 512-3841 or Shamesl@gao.gov.

What GAO Found

FDA is one of 15 agencies that collectively administer at least 30 laws related to food safety. This fragmentation is the key reason GAO added the federal oversight of food safety to its High-Risk Series in January 2007 and called for a governmentwide reexamination of the food safety system. We have reported on problems with this system—including inconsistent oversight, ineffective coordination, and inefficient use of resources.

FDA has opportunities to better leverage its resources. Efficient use of resources is particularly important at FDA because we found that its food safety workload has increased in the past decade, while its food safety staff and funding have not kept pace. GAO has recommended that FDA establish equivalence agreements with other countries to shift some oversight responsibility to foreign governments, explore the potential for certifying third party inspections, and consider accrediting private laboratories to inspect seafood, among other actions. We also reported that FDA and the U.S. Department of Agriculture (USDA) conduct similar inspections at 1,451 facilities that produce foods regulated by both agencies. To reduce overlaps, we recommended that, if cost-effective, FDA enter into an agreement to commission USDA inspectors at such facilities. FDA incorporated some of these recommendations in its *Food Protection Plan*.

FDA's *Food Protection Plan* also proposes some positive first steps intended to enhance its oversight of food safety. Specifically, FDA requests authority to order food safety recalls and issue additional preventive controls for high-risk foods, both of which GAO has previously recommended. However, more specific information about its strategies and the resources FDA needs to implement the plan would facilitate congressional oversight. FDA officials acknowledge that implementing the *Food Protection Plan* will require additional resources. Without a clear description of resources and strategies, it will be difficult for Congress to assess the likelihood of the plan's success in achieving its intended results.

The Science Board cites numerous management challenges that have contributed to FDA's inability to fulfill its mission, including a lack of a coherent structure and vision, insufficient capacity in risk assessment, and inadequate human capital recruitment and retention. In light of these challenges, GAO has identified through other work some tools that can help agencies improve their performance over time. For example, a Chief Operating Officer/Chief Management Officer can help an agency address longstanding management problems that are undermining its ability to accomplish its mission and achieve results. In addition, a well-designed commission can produce specific practical recommendations that Congress can enact. Critical success factors that can help ensure a commission's success include a statutory basis with adequate authority, a clear purpose and timeframe, leadership support, an open process, a balanced membership, accountability, and resources.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the resources the Food and Drug Administration (FDA) uses to meet one of its key regulatory responsibilities, the oversight of food safety. FDA is responsible for ensuring the safety of roughly 80 percent of the U.S. food supply, including $417 billion worth of domestic food and $49 billion in imported food annually. Contaminated food can harm human health, have severe economic consequences, and undermine consumer confidence in the government's ability to ensure the safety of the U.S. food supply. The recent outbreaks of *E. coli* in spinach, *Salmonella* in peanut butter, and contamination in pet food, highlight the risks posed by the accidental contamination of FDA-regulated food products. For example, according to FDA, the recent California spinach *E. coli* outbreak resulted in 205 confirmed illnesses and 3 deaths, and industry representatives estimate that economic losses ranged from $37 million to $74 million.

Changing demographics and consumption patterns underscore the urgency for effective food safety oversight. According to FDA, shifting demographics mean that more of the U.S. population is, and increasingly will be, susceptible to foodborne illnesses. The risk of severe and life-threatening symptoms from infections caused by foodborne pathogens is higher for older adults, young children, pregnant women, and immune compromised individuals. According to FDA, these groups make up about 20 to 25 percent of the U.S. population. In addition, we are increasingly eating foods that are consumed raw or with minimal processing and often associated with foodborne illness. For example, according to the U.S. Department of Agriculture (USDA), leafy greens such as spinach, are the category of produce most likely to be associated with an outbreak, and the average consumer ate 2.4 pounds of fresh spinach in 2005—a 180 percent increase over 1992.

In response to these increasing challenges, FDA and other agencies recently released plans that discuss the oversight of food safety. In November 2007, FDA released its *Food Protection Plan*, which sets forth FDA's framework for overseeing the safety of food.[1] Concurrently, a twelve-agency working group presented to the President its *Action Plan*

[1]Department of Health and Human Services, U.S. Food and Drug Administration, *Food Protection Plan* (Washington, D.C., 2007).

for Import Safety,[2] which contains, among other things, recommendations for improving the safety of food imports entering the United States. Both plans spell out numerous actions FDA plans to take to enhance food safety, including writing new food protection guidelines for industry and helping foreign countries improve their regulatory systems. The plans also request new legislative authorities. One requested legislative authority is for enhanced access to a food company's records during food safety emergencies. Subsequently, FDA's Science Board, an advisory board to the agency, released a report titled, *FDA Science and Mission at Risk*.[3] This report, which is the focus of today's hearing, concluded that FDA is not positioned to meet current or emerging regulatory needs, and stated that FDA does not have the capacity, such as staffing and technology, to ensure the safety of the nation's food supply. In addition, the report found that FDA's ability to provide its basic food system inspection, enforcement, and rulemaking functions is severely eroded, as is its ability to respond to outbreaks of foodborne illnesses in a timely manner and to develop and keep pace with the science needed to prevent food safety problems. The report stated that the system cannot be fixed using available resources, and its primary food safety recommendation was that FDA needs additional resources to fulfill its regulatory mandate.

I will focus on four key points: (1) federal oversight of food safety is a high-risk area that needs a governmentwide reexamination, (2) FDA has opportunities to better leverage its resources, (3) FDA's *Food Protection Plan* proposes some positive first steps but additional information on the plan's strategies and resources can facilitate congressional oversight, and (4) tools such as a commission or chief operating officer can help agencies to address management challenges. This testimony is based on new and previously issued work. Today, GAO is also testifying on another FDA regulatory responsibility—inspections of medical device manufacturers.[4] These and other recent testimonies on food and drug safety offer observations on FDA's management capacity.

[2]Interagency Working Group on Import Safety, *Action Plan for Import Safety* (Washington, D.C., 2007).

[3]FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (Washington, D.C., November 2007).

[4]GAO, *Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections*, GAO-08-428T (Washington, D.C.: Jan. 29, 2008).

To assess FDA's *Food Protection Plan*, we interviewed FDA officials; reviewed pertinent statutes and reports; and evaluated the plan using a GAO guide for assessing agencies' performance plans. To analyze data on FDA inspections, we examined data from FDA and determined that they were sufficiently reliable for our analyses. We also reviewed funding data from the Science Board and analyzed the data in real terms. To provide updated information on our previously issued reports, we gathered information on the status of our recommendations. We conducted our work in January 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Federal Oversight of Food Safety Is a High-Risk Area that Needs a Governmentwide Reexamination

While part of today's hearing focuses specifically on FDA's responsibilities for the oversight of food safety, it is important to note that FDA is one of 15 federal agencies that collectively administer at least 30 laws related to food safety. This fragmentation is a key reason we designated federal oversight of food safety as a high-risk area. Two agencies have primary responsibility—FDA is responsible for the safety of virtually all foods except for meat, poultry, and processed egg products, which are the responsibility of USDA. In addition, among other agencies, the National Marine Fisheries Service (NMFS) in the Department of Commerce conducts voluntary, fee-for-service inspections of seafood safety and quality; the Environmental Protection Agency (EPA) regulates the use of pesticides and maximum allowable residue levels on food commodities and animal feed; and the Department of Homeland Security is responsible for coordinating agencies' food security activities. This federal regulatory system for food safety, like many other federal programs and policies, evolved piecemeal, typically in response to particular health threats or economic crises.

In January 2007, we added the federal oversight of food safety to our High-Risk Series,[5] which is intended to raise the priority and visibility of government programs that are in need of broad-based transformation to achieve greater economy, efficiency, effectiveness, accountability, and sustainability. Over the past 30 years, we have reported on issues—for

[5]GAO, *High-Risk Series: An Update*, GAO-07-310 (Washington, D.C.: Jan. 31, 2007).

example, the need to transform the federal oversight framework to reduce risks to public health as well as the economy—that suggest that the federal oversight of food safety could be designated as a high-risk area. The fragmented nature of the federal food oversight system calls into question whether the government can plan more strategically to inspect food production processes, identify and react more quickly to outbreaks of foodborne illnesses, and focus on promoting the safety and integrity of the nation's food supply.

While we have reported on problems with the federal food safety system—including inconsistent oversight, ineffective coordination, and inefficient use of resources—most noteworthy for today's hearing is that federal expenditures for the oversight of food safety have not been commensurate with the volume of foods regulated by the agencies or consumed by the public. We have reported that four agencies—USDA, FDA, EPA, and NMFS—spent a total of $1.7 billion on food safety-related activities in fiscal year 2003.[6] USDA and FDA were responsible for nearly 90 percent of those federal expenditures. However, the majority of federal expenditures for food safety inspection were directed toward USDA's programs for ensuring the safety of meat, poultry, and egg products even though USDA is responsible for regulating only about 20 percent of the food supply. In contrast, FDA accounted for only 24 percent of expenditures even though it is responsible for regulating about 80 percent of the food supply.

Others have called for fundamental changes to the federal food safety system overall. In 1998, the National Academy of Sciences concluded that the system is not well equipped to meet emerging challenges.[7] In response to the Academy's report, the President established a Council on Food Safety which released a Food Safety Strategic Plan in January 2001. The plan recognized the need for a comprehensive food safety statute and concluded, "the current organizational structure makes it more difficult to achieve future improvements in efficiency, efficacy, and allocation of resources based on risk."

While many of the recommendations we made have been acted upon, a fundamental reexamination of the federal food safety system is warranted.

[6]GAO, *Overseeing the U.S. Food Supply: Steps Should be Taken to Reduce Overlapping Inspections and Related Activities*, GAO-05-549T (Washington, D.C.: May 17, 2005).

[7]Institute of Medicine, *Ensuring Safe Food from Production to Consumption* (Washington, D.C., 1998).

Taken as a whole, our work indicates that Congress and the executive branch can and should create the environment needed to look across the activities of individual programs within specific agencies, including FDA, and toward the goals that the federal government is trying to achieve. To that end, we have recommended, among other things, that Congress enact comprehensive, uniform, and risk-based food safety legislation and commission the National Academy of Sciences or a blue ribbon panel to conduct a detailed analysis of alternative organizational food safety structures.[8] We have also recommended that the executive branch reconvene the President's Council on Food Safety to facilitate interagency coordination on food safety regulation and programs. According to documents on the council's Web site, the current administration has not reconvened the council.

These actions can begin to address the fragmentation in the federal oversight of food safety. Going forward, to build a sustained focus on the safety and integrity of the nation's food supply, Congress and the executive branch can integrate various expectations for food safety with congressional oversight and through agencies' strategic planning processes, including FDA's. We have previously reported that the development of a governmentwide performance plan that is mission-based, is results-oriented, and provides a cross-agency perspective offers a framework to help ensure agencies' goals are complementary and mutually reinforcing. Further, with pressing fiscal challenges, this plan can help decision makers balance trade-offs and compare performance when resource allocation and restructuring decisions are made.

FDA Has Opportunities to Better Leverage its Resources

In response to the nation's fiscal challenges, agencies may have to explore new approaches to achieve their missions, and we have identified options for FDA to better leverage its resources. Efficient use of resources is particularly important at FDA because, while its food safety workload has increased in the past decade, resources have not kept pace. FDA has proposed actions toward implementing some of these options.

Our analysis of FDA data shows that while FDA received increased funding for new bioterrorism-related responsibilities in 2003, subsequent staffing levels and funding have not kept pace with the agency's growing

[8]GAO, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, GAO-02-47T (Washington, D.C.: Oct. 10, 2001).

responsibilities. Specifically, the number of FDA-regulated domestic food establishments increased more than 10 percent from fiscal years 2003 to 2007—from about 58,260 in 2003 to about 65,520 in 2007. Additionally, FDA notes that there have been dramatic changes in the volume, variety, and complexity of FDA-regulated products arriving at U.S. ports, and recently reported that the number of food import entry lines has tripled in the past ten years.[9] Meanwhile, staffing for FDA's Center for Food Safety and Applied Nutrition (CFSAN) has decreased. According to the Science Board, the number of staff years for CFSAN operations at headquarters dropped about 14 percent, from 950 in fiscal year 2003 to 812 in fiscal year 2006. During that same time period, field-based staff responsible for carrying out inspection and enforcement activities for CFSAN-regulated products dropped by 255 staff years, or about 11.5 percent—from 2,217 in fiscal year 2003 to 1,962 in fiscal year 2006. In addition, while CFSAN-related funding at headquarters and in the field increased from $407 million in fiscal year 2003 to $439 million in fiscal year 2006, this represents a decrease in real terms from about $457 million to about $451 million during that period. One consequence is that foreign inspections have declined: GAO analysis of FDA data shows that inspections of foreign food firms, which number almost 190,000, decreased from 211 in fiscal year 2001 to fewer than 100 in fiscal year 2007. The Science Board considered the funding issues to be more acute for CFSAN than for other FDA programs: unlike the FDA programs responsible for drugs, biologics, and medical devices, which charge manufacturers hundreds of millions of dollars in user fees each year, CFSAN is not authorized to charge user fees for its services.

Recent GAO work has identified opportunities for FDA to better leverage its resources. Specifically, in 2004 we reviewed FDA's imported seafood safety program and identified several options that FDA could consider to augment its resources and enhance its current program.[10] We found that FDA's seafood safety program had shown some progress from a 2001 review. For example, FDA increased its laboratory testing of seafood products at ports of entry from less than 1.0 percent in fiscal year 1999 to about 1.2 percent in fiscal year 2002. We also recommended several

[9]According to FDA, an entry line is each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately.

[10]GAO, *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed*, GAO-04-246 (Washington, D.C.: Jan. 30, 2004).

options for enhancing FDA's oversight of seafood while leveraging outside resources. Some of these options are presented in FDA's *Food Protection Plan*. We recommended that FDA:

- *Make it a priority to establish equivalence agreements with other countries.* Subject to its jurisdiction, FDA could certify that countries exporting food products to the United States have equivalent food safety systems before food products from those countries can enter the United States. Such agreements would shift some of FDA's oversight burden to foreign governments. While FDA has not yet established equivalence agreements with any foreign countries, the *Food Protection Plan* requests that Congress allow the agency to enter into agreements with exporting countries to certify that foreign producers' shipments of designated high-risk products comply with FDA standards.

- *Explore the potential for certifying third-party inspectors.* FDA could consider developing a program that uses certified third-party inspectors to conduct inspections on its behalf, both at foreign processing firms and domestic importers of seafood. FDA's *Food Protection Plan* requests authority from Congress to accredit third parties to conduct voluntary inspections for foods, and FDA officials told us that they envision using third-party inspectors to inspect foreign facilities, where FDA conducts few inspections. If FDA receives this authority, it can take lessons from its own implementation of third-party inspection programs for medical device manufacturing establishments. As we are reporting in a separate statement today, few inspections of these establishments have been conducted through FDA's two accredited third-party inspection programs.

- *Consider accrediting private laboratories to test seafood.* Currently, FDA does not accredit or use any private laboratories to collect or analyze seafood samples. However, for some seafood violations, it allows seafood firms to use private laboratories to provide evidence that imported seafood previously detained because of safety concerns is now safe and can be removed from the detention list at the port of entry. We recommended that FDA consider accrediting private laboratories because it could leverage outside resources while providing FDA greater assurance about the quality of the laboratories importers use to demonstrate that their products are safe. FDA has not formally changed its policies or practices, but the *Action Plan for Import Safety* notes that FDA intends to issue guidance by mid-2008 on sampling and testing of imported products, including the use of accredited private laboratories submitting data to FDA on food safety.

- *Develop a memorandum of understanding with the National Oceanic and Atmospheric Administration (NOAA) to use NOAA's Seafood Inspection Program resources to complete inspections on FDA's behalf.* NOAA officials said that they could provide various services to augment FDA's regulatory program for imported seafood, including inspection, training, and product sampling services. FDA has been working on a program to refer certain export-related work to NOAA, and it is in discussions with NOAA about commissioning its inspectors, but to date, nothing is finalized or operational.

We have not reviewed these actions to determine whether they adequately address our recommendations.

We separately reported on overlaps we identified in the federal oversight of food safety, such as overlapping inspection and training activities that exist among the agencies conducting food safety functions.[11] Such overlaps mean that federal agencies are spending resources on similar activities, which may waste scarce resources and limit effectiveness. Specifically, we found that FDA food safety activities may overlap with, if not duplicate, the efforts of other agencies, including USDA and NMFS. FDA could take practical steps to reduce overlap and duplication and thereby free resources for more effective oversight of food safety, but FDA has made little progress since our report. For example:

- *Domestic inspections.* In fiscal year 2003, FDA and USDA spent most of their food safety resources—about $900 million—on inspection and enforcement activities. A portion of these activities included overlapping and even duplicative inspections of 1,451 domestic food-processing facilities that produce foods regulated by both agencies. Under authority granted by the Bioterrorism Act of 2002,[12] FDA could authorize USDA to inspect these facilities on its behalf, but FDA has not yet reached an agreement with USDA to do this. We recommended that, if cost effective, FDA enter into an agreement to commission USDA inspectors at jointly regulated facilities. FDA told us that they are working with USDA to consider which products might be covered by each agency under such an agreement.

[11]GAO, *Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources*, GAO-05-213 (Washington, D.C.: Mar. 30, 2005).

[12]Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

- *Import inspections.* FDA and USDA both inspect shipments of imported food at ports of entry and also visit foreign countries that export food to the United States. We found that both FDA and USDA maintain inspectors at 18 U.S. ports of entry to inspect imported food. In fiscal year 2003, FDA spent more than $115 million on imported food inspections, and USDA spent almost $16 million. The two agencies do not share inspection resources at these ports. Although USDA maintains a daily presence at these facilities, the FDA-regulated products may remain at the facilities for some time awaiting FDA inspection. Further, FDA conducted inspections in 6 of the 34 countries that USDA evaluated in 2004 to determine whether their food safety systems for ensuring the safety of meat and poultry are equivalent to that of the United States. We recommended that FDA consider the findings of USDA's foreign country equivalence agreements when determining which countries to visit. In their response to our recommendation, the agency noted that they will consider USDA's foreign country evaluations when making such determinations.

- *Inspectors' training.* FDA and USDA spend resources to provide similar training to food inspection personnel. FDA spent about $1.6 million and USDA spent $7.8 million in fiscal year 2003. We found that, to a considerable extent, food inspection training addresses the same subjects, such as plant sanitation and good manufacturing practices. While other agencies have consolidated training activities that have a common purpose and similar content, FDA and USDA have not. We recommended that USDA and FDA consider joint training programs, but to date, FDA has told us that they have identified no training needs common to both agencies.

FDA's *Food Protection Plan* Proposes Some Positive First Steps, but Additional Information on the Plan's Strategies and Resources would Facilitate Congressional Oversight

FDA's *Food Protection Plan* proposes several positive first steps that are intended to enhance food safety oversight, including requesting several authorities recommended by GAO, but more specific information about its strategies and the resources needed to implement the plan would facilitate congressional oversight. Positively, FDA's *Food Protection Plan* aims to shift the agency's focus to prevention of foodborne illness instead of intervention after contamination and resulting illnesses occur—an important shift given that experts consider prevention to be a core element of an effective food safety system. FDA says that its key prevention steps are promoting corporate responsibility, identifying food vulnerabilities, assessing risks, and expanding its understanding and use of effective mitigation measures.

In addition to the actions we discuss earlier to address resource constraints, FDA's *Food Protection Plan* requests other authorities to

enhance oversight of food safety that begin to respond to prior GAO recommendations. Specifically, the plan requests authority for FDA to:

- *Order food recalls.* The *Food Protection Plan* requests the authority to order a recall when FDA has reason to believe that food is adulterated and presents a threat of serious adverse health consequences or death, to be imposed only if a company refuses or unduly delays conducting a voluntary recall. Currently, food recalls are largely voluntary—federal agencies responsible for food safety, including FDA, have no authority to compel companies to recall contaminated foods, with the exception of FDA's authority to require a recall for infant formula. FDA does have authority, through the courts, to seize, condemn, and destroy adulterated or misbranded food under its jurisdiction and to disseminate information about foods that are believed to present a danger to public health. However, government agencies that regulate the safety of other products, such as toys and automobile tires, have recall authority not available to FDA for food and have had to use their authority to ensure that recalls were conducted when companies did not cooperate. These agencies have the authority to require a company to notify the agency when the company has distributed a potentially unsafe product, order a recall, establish recall requirements, and impose monetary penalties if a company does not cooperate. In a report and testimony before this subcommittee,[13] we noted that limitations in the FDA's food recall authorities heighten the risk that unsafe food will remain in the food supply and have proposed that Congress consider giving FDA similar authorities. While FDA's *Food Protection Plan* requests mandatory recall authority, this request could also include recall authorities held by other agencies, including establishing recall requirements and imposing penalties for noncompliance. FDA officials noted that while recall requirements and penalties for noncompliance were not explicitly stated in the *Food Protection Plan*, they are encompassed in the request. Further, the plan does not propose a definition of "undue delay" by a company, another critical element of recall authority given that timing is essential in reacting to outbreaks, and delays can cost lives.

- *Issue additional preventive controls for high-risk foods.* FDA is requesting explicit authority from Congress to issue regulations requiring

[13]GAO, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, GAO-05-51 (Washington, D.C.: Oct. 6, 2004) and *Federal Oversight of Food Safety: High Risk Designation Can Bring Attention to Limitations in the Federal Government's Food Recall Programs*, GAO-07-785T (Washington, D.C.: Apr. 24, 2007).

foods that have been associated with repeated instances of serious health problems or death to be prepared, packed, and held under a system of preventive food safety controls. According to FDA, this would clarify the agency's ability to require industries to implement preventive Hazard Analysis and Critical Control Point (HACCP) systems, which it currently requires for companies that process seafood and juice. HACCP systems are designed to improve food safety by having industry identify and control hazards in products before they enter the market. FDA officials told us that they are asking for explicit authority to put measures in place for other high-risk foods, such as leafy greens. Officials told us that this request, if granted, would allow the agency to focus its preventive efforts on foods that present the highest risk for contamination, consistent with the agency's risk-based focus. However, others have expressed concern that requiring a history of repeated outbreaks before issuing preventive controls would not allow FDA to proactively establish regulations for foods before they cause additional illnesses.

While FDA officials have acknowledged that implementing the *Food Protection Plan* will require additional resources, FDA has not provided specific information on the resources it anticipates the agency will need to implement this plan. For example, the *Food Protection Plan* proposes to develop food protection guidelines for industry; however FDA's Science Board reported that modernizing safety standards for fresh produce and other raw foods and developing and implementing inspection programs could cost $210 million. Additionally, the *Food Protection Plan* proposes to enhance FDA's information technology systems related to both domestic and imported foods which the Science Board report suggests could cost hundreds of millions of dollars. FDA officials have declined to provide specific information on how much additional funding it believes will be necessary to implement the *Food Protection Plan*, saying that finalizing the amounts will take place during the budget process. Similarly, the *Food Protection Plan* does not discuss the strategies it needs in the upcoming years to implement this plan. FDA officials told us that they have internal plans for implementing the *Food Protection Plan* that detail timelines, staff actions, and specific deliverables. While FDA officials told us they do not intend to make these plans public, they do plan to keep the public informed of their progress. Without a clear description of resources and strategies, it will be difficult for Congress to assess the likelihood of the plan's success in achieving its intended results.

Tools that Agencies Can Use to Address Management Challenges

The Science Board cites numerous management challenges that have contributed to FDA's inability to fulfill its mission, such as a lack of a coherent structure and vision, insufficient capacity in risk assessment, and inadequate human capital recruitment and retention. The Science Board also noted that public confidence in FDA's abilities has diminished. In light of these challenges, we have identified through other work some tools that can help agencies improve their performance, which may also be relevant to FDA.

For example, we reported on the use of a Chief Operating Officer (COO)/Chief Management Officer (CMO) as one way to address longstanding management problems that are undermining agencies' abilities to accomplish their missions and achieve results.[14] Agencies with such challenges, including FDA, could benefit from a senior leader serving as a COO/CMO who can elevate, integrate, and institutionalize responsibility for key management functions. While GAO has long advocated the need for a COO/CMO position at the Department of Defense and the Department of Homeland Security, a relatively stable or small organization could use the existing deputy or related position to carry out the role. In addition to GAO, a number of other organizations have supported the need for the creation of COO/CMO positions in federal agencies. McKinsey & Company recommended that a COO be established in many federal agencies as the means to help those agencies successfully achieve transformation.[15] In addition, a working group within the National Academy of Public Administration (NAPA) recommended creating COO positions in federal agencies to oversee the full range of management functions, including procurement, finance, information technology, and human capital.[16]

Another tool that can help federal agencies address their management challenges is a well-designed commission that can produce specific practical recommendations that Congress can enact. For example,

[14]See for example, GAO, *A Call for Stewardship: Enhancing the Federal Government's Ability to Address Key Fiscal and Other 21st Century Challenges*, GAO-08-93SP (Washington D.C.: November 2007) and *Organizational Transformation: Implementing Chief Operating Officer/Chief Management Officer Positions in Federal Agencies*, GAO-08-34 (Washington, D.C.: Nov. 1, 2007).

[15]McKinsey & Company, *How Can American Government Meet its Productivity Challenge?* (July 2006).

[16]NAPA, *Moving from Scorecard to Strategic Partner: Improving Financial Management in the Federal Government* (October 2006).

Congress created the National Commission on Restructuring the Internal Revenue Service (IRS) in 1995 to review current practices at IRS and report on requirements for improvement. Congress subsequently passed the IRS Restructuring and Reform Act of 1998, which was influenced by the Commission's report, and reorganized the structure and management of IRS, revised the mission of IRS, and mandated numerous other detailed changes.[17] Based on our recent analysis of several commissions, there are several critical success factors that can be applied to ensure a commission's success including:[18]

- *A statutory basis with adequate authority.* When provided with a clear mandate and adequate authority, a commission can comprehensively access and analyze information related to a given policy issue and thereby provide more informed policy options for the President and Congress to consider.

- *A clear purpose and timeframe.* A commission should have a clear purpose for its objectives and activities to help guide the members in carrying out their responsibilities. In addition, a fixed agenda and timeframe can help keep a commission focused and on track. However, a commission should have a broad enough scope to help ensure it has the authority to address all the issues necessary in order to come up with a comprehensive and integrated solution without encountering any constraints in the process as to what it can or cannot consider.

- *Key leadership support.* Institutional leadership, commitment, and support from the President and Congress are necessary to help a commission succeed.

- *An open and transparent process.* By having an open and transparent process, such as public hearings, a commission can help build consensus among the public for its goals by gaining their input and support.

- *A balanced and capable membership.* Balanced and capable membership can help lessen political influences and build consensus among the commission members when carrying out its purpose. Specifically, a commission should involve current or former Members of Congress as well as experts and professionals on the topic. Current or former elected

[17]Pub. L. No. 105-206 (July 22, 1998).

[18]GAO, *Long-Term Fiscal Challenge: Comments on the Bipartisan Task Force for Responsible Fiscal Action Act*, GAO-08-238T (Washington, D.C.: Oct. 31, 2007).

officials can ensure viability of a commission's legislative proposals due to their experience.

- *Accountability.* Clear accountability for a commission can help foster specific, useful outputs that could help inform the public and provide specific policy options and, hopefully, recommendations for Congress and the President.

- *Resources.* The success of the commission is dependent on having the adequate resources to carry out its purpose and any potential recommendations.

Generally, one concern regarding commissions may be whether or not there is sufficient buy-in from key stakeholders on the purpose of the commission along with a commitment to act on any resulting recommendations. Any recommendations by a commission in a final report are generally advisory in nature and may not automatically result in any public policy changes. Congressional action through subsequent legislation with Presidential support may be necessary for the commission's recommendations to be implemented and for any changes to occur.

Food safety concerns not only continue but will likely become more urgent in view of changing demographics and consumption patterns. Clearly, FDA plays a critical role in the federal oversight of food safety because of the breadth of its responsibilities. Thus its ability to carry out those responsibilities is necessary to help ensure the safety of the nation's food supply in the most efficient, effective, accountable, and sustainable way. Nevertheless, in light of the federal government's long-term fiscal challenges, agencies, including FDA, need to seek out opportunities to better leverage their resources. FDA's *Food Protection Plan* is a step in the right direction and proposes to implement many of the recommendations made by GAO. However, additional information on the strategies and resources needed to implement the plan can help Congress assess the likelihood of its success. Further, concerns over FDA's management challenges, such as those identified by the Science Board could hinder the implementation of the plan. Tools such as commissions and positions like a COO/CMO can help agencies address management challenges and make needed progress to achieve their missions. Continued congressional oversight, including today's hearing, and additional legislative action are key to achieving that progress and to promoting the safety and integrity of the nation's food supply.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions that you or other Members of the Subcommittee may have.

Contact and Staff Acknowledgments

Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. For further information about this testimony, please contact Lisa Shames, Director, Natural Resources and Environment at (202) 512-3841 or shamesl@gao.gov. Key contributors to this statement were Candace Carpenter, Bart Fischer, José Alfredo Gómez, and Alison O'Neill.

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Mr. STUPAK. Thank you, and thank you for your testimony.
Dr. Porter, your opening statement, please.

STATEMENT OF DONNA V. PORTER, PH.D., R.D., SPECIALIST IN FOOD SAFETY AND NUTRITION, DOMESTIC SOCIAL POLICY DIVISION, CONGRESSIONAL RESEARCH SERVICE

Ms. PORTER. Thank you, Mr. Chairman. I would like to thank you and the members of the subcommittee for inviting me to speak today. My name is Donna Porter. I am a specialist in food safety and nutrition in the Domestic Social Policy Division of the Congressional Research Service. I am accompanied today by my colleagues, Judith Johnson, Susan Thaul and Erin Williams. Today, CRS is releasing a report that is a 28-year history of the FDA's budgetary and statutory authority. I would ask that the full report be included in the hearing record.

CRS takes no position on whether the FDA has the necessary resources to meet its statutory responsibilities. However, the report that we have prepared examines the agency's budget and increasing statutory authority since 1980. It is intended to help inform the debate on whether FDA's budget has kept pace with the increasing demands that have been placed on the agency.

In response to the CRS request for historic data, FDA cited constraints on its staff time and indicated it would only be able to provide data to us for very recent years. The data in the report that we have completed was taken from the annual FDA Budget Justification documents, which despite some limitations provide reasonably consistent information over time.

I would like to describe four figures that are in the report that I feel illustrate how the agency has fared in the last quarter-century. Figure 1 shows the 28-year history of the FDA budget and FTEs. Direct congressional appropriations to the agency, adjusted for inflation, doubled during the time period that we looked at. Over that same time, FDA received a 12-fold increase in other funds, primarily user fees. As a result, the overall FDA budget in fiscal year 2007 is 2½ times what it was in fiscal year 1980.

Personnel, measured as full-time equivalent positions, or FTEs, reflects a similar impact of user fees. Comparing the fiscal year 1980 budget with fiscal year 2006 budget, the last year for which complete FTE data was available, budget authority-funded FTEs stayed about the same and the FTEs funded by user fees increased 4-fold. Overall, there was a 19 percent increase in total FTEs.

In general, direct appropriations have either been in line with inflation or have gradually increased over time. The exception was in fiscal year 2002, when Congress increased direct appropriations to FDA by 23 percent in response to the domestic terrorist attacks and the anthrax scare.

In figure 2, we have presented the FDA's food budget and FTEs, and let me just say parenthetically the figures in my testimony are numbered differently in the full report when you go to the full report. Overlaid on this graph are the 11 major statutes that were added to responsibilities to the food program since 1980. Funding of the foods programs does not include user fees, as you are all well aware. The slight budget increases in the early 1990s can be attributed to the passage of the Nutritional Labeling and Education Act

and the somewhat larger increase in the late 1990s can be attributed to former President Clinton's Food Safety Initiative. Funding increased markedly following the 2001 domestic terrorist attacks but since then the foods budget has remained flat at its higher level.

In figure 3, we have the human drugs budget and FTEs with an overlay of the 14 new major statutes adding responsibility to its program. This provides an interesting contrast to the food programs' grab that we just looked at because of the impact of user fees that have primarily supported drug review. The apparent increase in FTEs and dollars in fiscal year 1983 through fiscal year 1987 reflects an agency reorganization that combined human drugs and biological activities during that 5-year period. We determined there was no way to decipher how much was spent in each area during those years so we just left them combined.

Starting in fiscal year 1994, user fees, which are the upper parts of the bars that you are looking at, have become an increasingly proportion of the overall resources available for human drugs while at the same time congressional appropriations have remained relatively flat. This figure also shows with the growing gap between the two FTEs that the overall increase in human drugs personnel is supported by user fees.

Finally, figure number 4 shows some information about FDA's research program, which supports its regulatory mission. The figure represents a 15-year history of FDA research spending in the five major areas: foods, human drugs, biologics, animal drugs and devices. Overall, the FDA research budget in fiscal year 2007 has declined by about 50 percent since fiscal year 1993. Unfortunately, this was as far back as the data was available for us to use.

Mr. Chairman, that completes my testimony. My colleagues and I would be pleased to address any questions that you and the committee may have.

[The prepared statement of Dr. Porter follows:]

Testimony Before the
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Donna V. Porter, Ph.D., R.D.
Specialist in Food Safety and Nutrition
Domestic Social Policy Division
Congressional Research Service
Library of Congress
January 29, 2008

Thank you, Mr. Chairman and Members of the Committee, for this opportunity to speak before you. My name is Donna Porter, Specialist in Food Safety and Nutrition, Congressional Research Service. I am accompanied by Judith Johnson, Susan Thaul, and Erin Williams. Today, CRS is releasing a report that is a 28-year history of the FDA's budget and statutory authority. I would ask that the full report be included in the hearing record.

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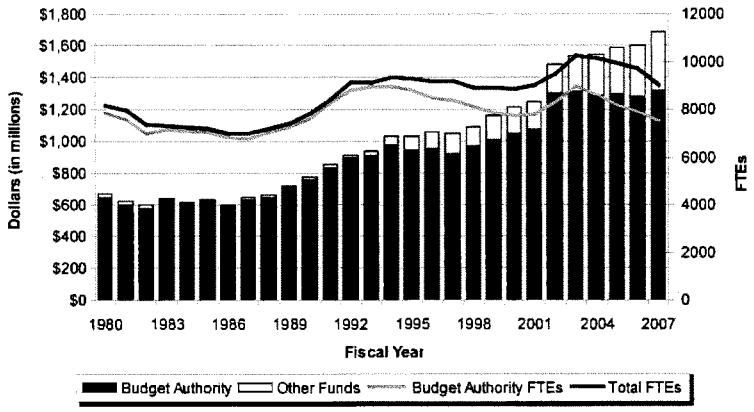
Four figures from the report illustrate how the agency has fared in the last quarter century.



Source: FDA *Justification of Estimates for Appropriations Committees* documents.
Notes: Total FTEs = Budget Authority FTEs + User Fee FTEs. Program Level $ = Budget Authority $ + User Fees $.

Figure 1 shows the 28-year history of the FDA budget and FTEs. Direct congressional appropriations (budget authority) to the agency, adjusted for inflation, doubled over the past quarter century. Over the same time, FDA received a 12-fold increase in other funds, primarily user fees. As a result, the overall FDA budget in FY2007 is 2 ½ times that in FY1980.

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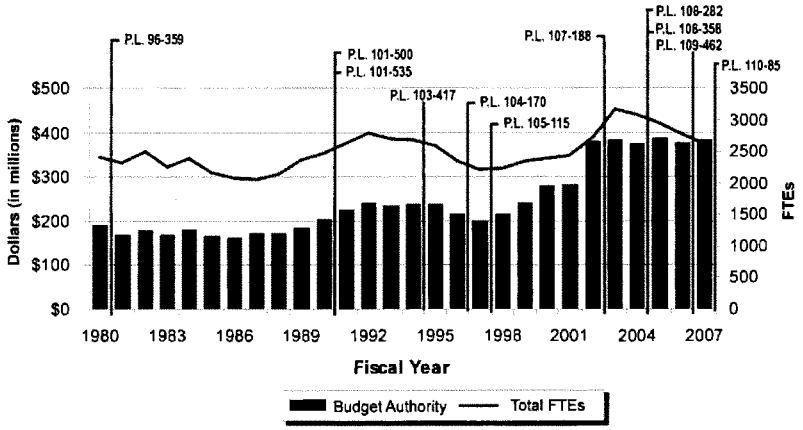

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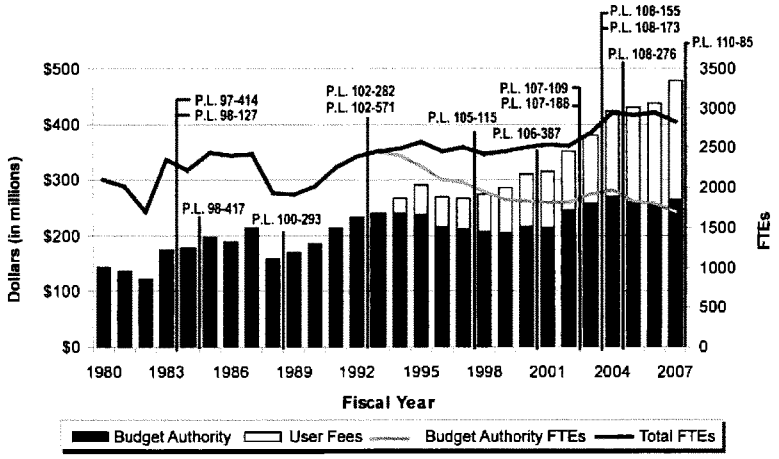
Figure 2 shows the FDA's Foods budget and FTEs. Overlaid on the graph are the 11 statutes that added responsibilities to the program since 1980. Funding of the Foods program does not include user fees. The slight budget increase in the early 1990s was in response to the passage of Nutrition Labeling and Education Act and the somewhat larger increase in the late 1990s can be attributable to former President Clinton's food safety initiative. Funding increased markedly following the 2001 domestic terrorist attacks, but since then the Foods budget has remained flat at its higher level.



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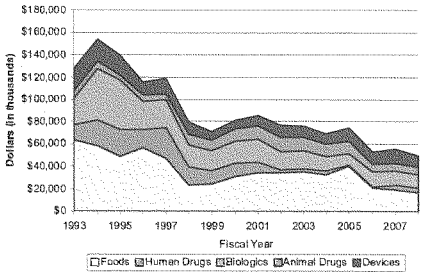
Starting in FY1994, user fees — the upper section of the bars — have become an increasing portion of the overall resources available for Human Drugs, while congressional appropriations remained relatively flat. This figure also shows — with the growing gap between the FTE lines — that the overall increase in Human Drugs personnel is supported by user fees.



Source: RAND Corporation RaDiUS database, November 7, 2007.

FDA conducts a research program that supports its regulatory mission. Figure 4 provides a 15-year history of FDA research spending in the five major activity areas: Foods, Human Drugs, Biologics, Animal Drugs, and Devices. Overall the FDA research budget in FY2007 has declined by about 50 % since FY1993.

Mr. Chairman, that concludes my testimony. My colleagues and I would be pleased to address any questions that you and the Committee may have.

Mr. STUPAK. Thank you, and thank you all for your testimony.

Dr. Crosse, let me start with you, if I may. Did your audit find that one database at the FDA showed that their foreign inspections, the roughly 3,000 that there be in existence, roughly 3,000 foreign firms and another database showed there is approximately 7,000 foreign firms sending drugs here to this country?

Ms. CROSSE. That is correct. One system showed about twice as many firms shipping drugs to the United States as were registered in the other system.

Mr. STUPAK. OK. And your report also found the FDA was having significant difficulty with their statutory mandate regarding these drug inspections. In fact, despite the experts telling this committee that drug firms should be inspected about once every 2 years, your audit found that overseas FDA was only able to inspect on an average of once every 13 years?

Ms. CROSSE. That is correct. We estimate that without any growth in the number of firms overseas, at the current rate they would only be able to get there about once every 13 years.

Mr. STUPAK. OK, and then in medical devices, FDA by statute again is supposed to inspect firms every 2 years domestically and that has taken as much as 6 years to inspect high-risk firms making class III devices?

Ms. CROSSE. That is correct. The firms that are making such devices as cardiac stents and the catheters that are used in angioplasty procedures, and pacemaker electrodes, those firms are being inspected about once every 6 years.

Mr. STUPAK. OK, and then class II medical devices, they are being inspected about once every 27 years?

Ms. CROSSE. At their current rate, they are getting there about once every 27 years. That is correct, for the foreign firms.

Mr. STUPAK. So if I am the FDA Commissioner, I am trying to figure out what to do, would it be smarter then to use the limited resources—we heard a lot about resources in the last panel and I know you sat through these panels. Would it be smarter then to direction to class III or to class II, or can you not do it that way, prioritize it by severity or health risk of the device being implanted in a human body?

Ms. CROSSE. Well, I think they are doing some prioritization. Clearly they are putting more resources into getting to the class III device establishments more frequently than the class IIs but they are not making that choice completely to go to the class III facilities, to get to all of the class III facilities before they do class IIs. That is a choice they have not made.

Mr. STUPAK. Well, the FDA recently announced last week that they are going to establish offices overseas and especially like China and India. Does the FDA have the regulatory authority overseas to do what has to be done for a class II or class III medical device inspection? Is there some question about that?

Ms. CROSSE. Well, certainly they don't have the same authority to demand entry at a facility overseas as they do in the United States but they do have the ability to stop those products from being imported if those manufacturers do not cooperate in an FDA inspection. I think it is a very positive thing that they are trying to establish some presence overseas because part of what these

staff in the countries could do is just to verify the information that is in the registration system to even determine what facilities exist, where they are located and what they are making.

Mr. STUPAK. Well, besides just establishing an office overseas, should you not have some kind of verification system of manufacturing practices and certify the plant or the labs that are producing these devices, especially for a class III device?

Ms. CROSSE. We certainly think the inspections are absolutely needed as well. It is not just the verification. We believe that they do need to be inspecting facilities at the manufacturing site.

Mr. STUPAK. Thank you.

Ms. Shames, let me ask you this. On page 11 of your testimony, and you repeated it but I just want to—you note, and I am quoting, "FDA officials have declined to provide specific information on how much additional funding it believes will be necessary to implement the Food Protection Plan, saying that finalizing the amounts will take place during the budget process." Do you have any confidence that what will be proposed in the budget process will be anything close to what may actually be needed to implement these plans?

Ms. SHAMES. Well, of course we will have to see what does come out in the President's budget that will be released in February. Just give some examples again from the Science Board, to update some of the guidelines, the food safety guidelines that we are talking about, the Science Board estimates that it will cost over $200 million. To update the IT system that was discussed earlier, they said that it would cost hundreds of millions of dollars. So FDA acknowledges that it is going to cost more money but does not provide any specifics.

Mr. STUPAK. In the past couple years' budget areas that you looked at, has the FDA ever asked for a significant amount of money to improve or implement these plans?

Ms. SHAMES. Well, in fact, the appropriations have gone up slightly on the food side. In nominal terms they have gone up slightly. In real terms they have actually declined. The point that we have noted over the last couple of years is that GAO has made numerous recommendations where FDA could leverage its scarce resources by working with USDA to work jointly with some of the training and some of the inspections. FDA can bring in other parties as part of the food inspection, for example, looking for equivalence agreements. It is only now in the Food Protection Plan that was released a couple of months ago that FDA appeared to be moving forward with that.

Mr. STUPAK. Dr. Porter, let me ask you, if I may, on page 11 of your report is the following statement: "Some members of Congress have also expressed concern over FDA funding level and have voiced their frustration at the inability to obtain clarification from the agency on the adequacy of the FDA budget." Your report then goes on to describe that many FDA commissioners have while in their official positions said that the agency does not need resources yet when they leave the agency they tell a different story. In fact, you quote former Commissioner Donald Kennedy who said the following, and I quote, "I hope you and your staff will be diligent in pursuing FDA resource needs but you may have to rely on grizzly veterans like me because budget authorities at HHS and OMB spe-

cifically prohibit present officials in the agency from speaking out publicly about the need for more funding. It is important that the American public know that when they hear FDA officials say they are satisfied with their budget allocations, they have their fingers crossed under the witness table."

Dr. Porter, as an expert on budget matters and given the extensive concerns related to the lack of resources at the FDA as described in the Science Board report, how would you advise Congress to obtain the accurate figure of what the FDA truly needs to protect the American public?

Ms. PORTER. Well, Mr. Chairman, those kinds of comments from Donald Kennedy and others were very consistent. There were lots more of them that we might have put in the report but it would have been totally redundant. What we did discover was, there are several alternatives that are used by other agencies in terms of communicating with Congress. One of those is the professional judgment budget that Congress frequently asks the CDC for and the alternative budget that the National Institutes of Health Cancer Center provides, and I think that perhaps there are some alternatives like those kinds of mechanisms that might be used that Congress could explore with the agency as ways to have something that doesn't go through the normal budget process and filters out perhaps what the agency believes is needed for various priorities.

Mr. STUPAK. Well, I know like veterans have the independent budget and then there are other organizations. Is there any organization outside of the FDA that would advocate for a different budget, an independent budget, a professional budget, whatever you want to call it, has there ever been an organization that would do that other than the Science Board that gave their recommendations today?

Ms. PORTER. Well, I am not aware of anything until very recently. I mean, there is, you know, considerable literature out there where people have talked about the agency's problems over the years but I think that it has been more individuals until very recently when the alliance was formed of people who are former agency officials, commissioners, secretaries of health and various other high-ranking people, who have expressed considerable concern and much of their experience is from inside knowledge of the agency. Now that they have stepped away from the agency, they are more comfortable I think with expressing what they feel is needed for the agency so that it can go forward.

Mr. STUPAK. Right, and Mr. Hubbard has testified once or twice before this committee but that is recent vintage. I don't know of any other organization or group.

Ms. PORTER. I am not aware of any other organizations per se. Well, there have been a couple of organizations out there who feel that what FDA does is that they have too much authority and they shouldn't be doing some of the things——

Mr. STUPAK. Well, you are always going to find that.

Ms. PORTER. Those are the only other organizations I know of.

Mr. STUPAK. Thank you.

Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. I appreciate the second panel being here. Sorry about how crazy our lives are.

Dr. Porter, 1980, is there a reason why 1980 was chosen? How far—I mean, in a timeline of the FDA, which is very old, why 1980?

Ms. PORTER. I should start by saying I climbed on board at CRS in 1980 so my——

Mr. SHIMKUS. It works for me.

Ms. PORTER. But more importantly, that was the year that Mr. Reagan was elected President and he wasn't real hip on regulatory agencies and started a major effort to re-regulate parts of the government or at least do regulatory reform, and in some of my reading back over what had happened in the last 30 years, that seemed to be a good point at which to start to look at where FDA as well as many other regulatory agencies were falling behind in terms of the budgets that they had, you know, had up until that point and the cutbacks began.

Mr. SHIMKUS. The issue is the 1980, 1981 would be really Carter Administration budgetary numbers, fiscal year.

Ms. PORTER. Yes, just for a year though.

Mr. SHIMKUS. Just raising that for the sake of clarity and transparency. Let me move on because——

Ms. PORTER. We had budget documents going back that far so that partly was our starting point since we were unable to get the information out of the agency.

Mr. SHIMKUS. Right. That is fine. Resourcing is a clear issue that has been raised, and I think that has been really well vetted. I think there is valid concern. In the chairman's opening statement, and I felt very proud to hear it, was that it is not always resourcing, it is also efficiency, it is also management, it is also transforming. You go from 1980 until today: Who heard about biologics? Who heard about the importation? Third World countries sending drugs to this country? And it is really a different era. So my focus will be, again, accepting the premise that resourcing has been vetted, what about management? And I want to turn to Dr. Crosse. You encountered in your evaluation at the FDA some problems that also were not just resource identified. Is that correct?

Ms. CROSSE. Yes, I would say so, although we were not doing a systematic evaluation of the management of the program. In trying to gain information from the agency, we asked for such things as copies of whatever monthly reports they put together, whatever information they might have for managing their resources and how they were allocating their workload, at what rate staff were meeting the established goals, and we were told that they don't have such reports. Now, how much of that is traceable to IT problems, I can't say, but clearly they were not setting out with the mindset of trying to manage the program and all of the human resources that they have in place. It just wasn't the way they were approaching this work.

Mr. SHIMKUS. Which is a valid point. Our Federal employees do a great job, given the paradigm that they find themselves in Federal agencies, but many of us believe—of course, they don't have the pressure that is placed on them from the competitive market to not only provide a great service at a low cost but also when business has to do that, they are going to be held accountable for the safety of that through litigation system or through consumers fleeing the product, and so the built-in process of reevaluation some-

times you don't find in a Federal agency. Is there anything you can point to, an example of where that might be true in the FDA evaluation?

Ms. CROSSE. Well, I don't think I would put it down to the lack of the kind of competitive pressures that exist in the private sector.

Mr. SHIMKUS. I am a competitive-market Republican so I believe that everything is solved by that.

Ms. CROSSE. I mean, I think these folks are working extremely hard to try to work within the limited resources that they have. I think to some extent, or at least in some parts of the organization, that the mindset though is more of trying to deal and wrestle with some of the scientific challenges that they have rather than taking an orientation to specifically try to manage it in the way that someone with an MBA background might.

Mr. SHIMKUS. Right, and I think that is the flipside of this coin on resourcing is, management—I mean, we are willing to talk about resourcing with the Majority but of course there will be a desire to see results and real transformation of an agency to be able to be accountable, to be able to pull up documents, to be able to follow through the processes and not experience the difficulties that some folks had in trying to gather information, and I hope that we move in that direction.

Mr. Chairman, I yield back.

Mr. STUPAK. Let me ask a couple questions while all the members are coming down here. We were talking earlier about not getting the numbers, financial numbers as to some of these plans. Back in November, the President's Interagency Working Group on Import Safety submitted this action plan for import safety. This is November of 2007. And then the other one again right around November, again November 2007, Food Protection Plan. Did any of you come across any evidence that these were being implemented, either the Food Protection Plan or the Plan for Import Safety?

Ms. SHAMES. Both documents are high-level frameworks of proposed actions. At least for the Food Protection Plan, we found that those proposals are consistent with recommendations that GAO has made over the last couple of years and that is why we feel as a start it is very positive.

Mr. STUPAK. Well, they recognized it, but did they begin implementing it?

Ms. SHAMES. No, no, we are told that their implementation plans have specific time frames, deliverables, accountable parties. We are told that they are not going to be made public, and while we recognize that implementation plans need to be nimble and flexible and the real world is very dynamic, on the other hand certain transparency helps in terms of accountability, allows you to see exactly what progress is being made. Likewise plans can engender some buy-in for what FDA's priorities ought to be. There is a shortage of resources and clearly there needs to be some sort of priority.

Mr. STUPAK. In fact, actually in your testimony you said, "Without a clear description of resources and strategies, it will be difficult for Congress to assess the likelihood of the plan's success in achieving the intended results." It would be also difficult to get any kind of resource commitment from Congress if we don't know what the plan is.

Ms. SHAMES. Exactly.

Mr. STUPAK. Are these the ones where you couldn't get any monetary, the resources it would take or the cost it would take to implement these plans? You could not get the financial information? Is that correct?

Ms. SHAMES. Well, we are interested in more detailed information overall, but certainly in light what the Science Board is saying for resources, that of course is of critical importance. We have noted too though that FDA is one of 15 agencies. So if are you looking at food safety, it really needs to be looked at from a government-wide perspective. There is a structural imbalance in terms of the resources that USDA gets versus FDA despite the responsibilities that each agency has.

Mr. STUPAK. Let us go from food safety to drug safety, Dr. Crosse. I read somewhere that about 80 percent of the active ingredients for pharmaceuticals come from overseas now.

Ms. CROSSE. That is my understanding, yes.

Mr. STUPAK. OK. And we were talking about inspection earlier, like 27 years for class II medical devices. I am looking at your report, page 25. It is table number 2, the FDA's inspection of foreign establishments involved in the manufacture of drugs in the U.S. market, and China by far is the largest. It has grown since 2002 to a number up there, 714 different establishments, we believe, but yet they are only inspecting 10 to 15 per year, correct?

Ms. CROSSE. That is correct, yes.

Mr. STUPAK. So if you have 714, we are inspecting 10 to 15 per year, if my math is correct, that would be about 40 to 50 years before you would get around to inspecting them again.

Ms. CROSSE. Yes, if the rates do not increase, that is correct.

Mr. STUPAK. Now, India and China are the largest producers of these pharmaceutical ingredients that are coming here to the United States. When you open an office in India or China, you still need some kind of a jurisdiction to make the number and resources to make the inspections that are necessary to close that gap of 40 to 50 years down to 2 or 3 years as it is domestically, correct?

Ms. CROSSE. Yes, they would have to add resources to be able to do that.

Mr. STUPAK. The question is probably obvious, but would you explain to us why is it important that you have these inspections? What is so important about it? How do you guarantee the safety of the drug being made or the pharmaceutical being manufactured? Just explain in your own words for pharmaceuticals and medical devices, why is it so important to do these inspections?

Ms. CROSSE. Well, I think they need to go to the facilities to see what kind of physical infrastructure exists in these locations, to see what the production lines are, to see what kind of quality control procedures the facility has in place, how they are doing their own testing and measurement of either the drugs or the devices, to ensure that they are meeting the specifications. These are not products that one can readily just check at the border in the way that you can take a small sample from a food shipment perhaps and send to the lab. A medical device may be a very expensive piece of equipment. They may come in small quantities. You would have to essentially destroy that piece of equipment in order to test it

against specifications, or it would no longer be sterile. So your best approach there is to actually see what kind of production line is in place and what kind of quality procedures that company has to ensure production of a piece of equipment.

Mr. STUPAK. Well, isn't this what the FDA has said in some of these reports that what the FDA calls building quality into the system? Is that what they are talking about by doing more inspections at the manufacturing site?

Ms. CROSSE. Well, I think that is one component of what they are talking about. I think there are a number of kinds of checks and balances that they hope to put in place but certainly inspections are one piece of that.

Mr. STUPAK. Thank you.

Mr. Shimkus?

Mr. SHIMKUS. Just for a second, Mr. Chairman, just to follow up on this debate. My colleague makes a good point in the setup of this discussion. We will never have enough resources. If the growth continues in these areas, I mean, how do we ever get there? So what we will need is, what is the solution? Where should we go or how do we manage this? I don't know if we have the answer but that is the great thing about the Oversight and Investigation Subcommittee. We start posing the questions, and the committee's jurisdiction, part of us will start trying to address those, but maybe it is training and really international agreements based upon training in which we are partnering with these countries that want access to our markets where we are spreading the risk and we can be assured of the quality. Otherwise if we expect it to all be done in our arena, I am not sure how we ever get there, but it is a great question and I just pose that as a solution. There are probably many more. But that is a concern. I don't know if anyone wants to comment on that. Dr. Crosse?

Ms. CROSSE. I would just comment, I mean, I think something like the accredited persons inspection program held great promise. It held out the possibility of a company having one inspection performed to meet the requirements of multiple countries, so many of these are international firms. I think the great disappointment there is that it has not been taken up by industry. Really, industry has been very, very slow and in fact has been slow to cooperate in allowing the inspectors to be trained to participate in this program. And so that would have provided or may still yet provide an opportunity to leverage resources where you are not having to just build the FDA inspection force, you have outside inspectors who can be accredited to do the inspections to meet the standards of all of these countries. So far it has been very, very slow in taking off.

Mr. STUPAK. If I may, but why would you go to a voluntary inspection plan if you know the FDA isn't going to show up for at least 27 years, or if it is active pharmaceuticals, 40 to 50 years, why would I, as a manufacturer, why would I submit myself to a voluntary thing because I know they will never come?

Ms. CROSSE. I think that is one of the reasons that it has not taken off more quickly. I would agree that given the very low rate of inspections by FDA in some of these countries, there is no incentive.

Mr. SHIMKUS. I don't have anything to add other than we would just hope for better, and I appreciate the time. Thank you, Mr. Chairman.

Mr. STUPAK. This idea about opening offices overseas came up last fall after we had our inspectors in China and India, both the Minority and Majority staff were over there in August and they came up with great ideas, and that was just one of them. I think we will have the Commissioner next and we can explore that a little bit further with him.

Thank you to this panel. Thank you very much for your time and your insight into this issue. Thank you.

We would now like to call our last witness and the third panel would be Dr. Andrew von Eschenbach, Commissioner of the FDA. It is the policy of this subcommittee to take all testimony under oath. Please be advised, sir, that you have the right under the rules of the House to be advised by counsel during your testimony. Do you wish to be represented by counsel?

Dr. VON ESCHENBACH. No, sir.

Mr. STUPAK. OK. You are already standing, so we will take the oath.

[Witness sworn.]

Mr. STUPAK. Let the record reflect the witness replied in the affirmative. You are now under oath, sir. If you would please give your opening statement, and thank you for being here and thank you for sitting through this hearing today. We appreciate it.

STATEMENT OF ANDREW C. VON ESCHENBACH, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Dr. VON ESCHENBACH. Thank you very much, Mr. Chairman, Mr. Shimkus and members of the subcommittee. I want to truly express my gratitude to you and your colleagues for the opportunity to discuss the importance of maintaining a strong scientific foundation at FDA. This is the science that is necessary to enable the agency to not only respond to a rapidly and radically changing world but even more important to lead the future of FDA's regulatory processes and decisions. Our work must be both science-based and led by science.

I have invested my entire professional career in the world of scientific discovery and development that has led and made possible fields like genomics and molecular biology and frankly a whole host of disciplines that were unknown when FDA began its mission to protect and promote the public health or even a few decades ago. However, this science now makes it possible to do things like protecting and eliminating chemical and microbial contamination of water, our food and the environment. This science can give hope to patients with incurable cancer, to those living with AIDS or diabetes or in fear of Alzheimer's, stroke or heart disease. So as science makes these solutions possible, it is and must be science that will enable the FDA to ensure that these solutions, these products are safe and efficacious when they are delivered to the American people. As Commissioner of Food and Drugs, I take that responsibility very seriously to be able to modernize and improve FDA's scientific infrastructure as it is a critical element for success in the future of our regulatory mission. But the real questions, Mr. Chairman,

are what science and how best to create a portfolio that is different because by its very nature of its regulatory purpose, the science and research being conducted at FDA is unique and different from that at NIH and academia and perhaps even in industry.

Mr. Chairman, based on all my experience, I know that FDA must ask the question not whether our science is excellent but more importantly, is our science aligned for the challenges of today and of tomorrow. And in order to help address that issue and issues regarding our scientific portfolio, I asked the chairman of our Scientific Advisory Board to help us look ahead. The Board reached out beyond its membership to include ad hoc experts to make up a subcommittee to conduct the review. They worked for nearly 12 months to prepare the report that we are discussing today. Let me state, I am extraordinarily grateful for the incredible hard work and productivity of this committee and they have provided important insights into both the opportunities and the challenges facing the agency. I take their report very seriously and I want to assure them and the committee that it will be used to formulate the initiatives and serve as a basis for resource investments that will perpetuate the scientific excellence of FDA as a regulatory agency.

We already have work underway to address some of the challenges and opportunities that they have defined. Let me focus on one brief example to confirm the statement. Allow me to address an issue of information technology, which was a major theme of the report and something that has been highlighted repeatedly in today's testimony and even by your opening statement. FDA needs a modern information technology infrastructure to support a science-based and a science-led regulatory agency, and if I could have the chart portrayed for you or the graphic that is up on the screen.

[Slide.]

In 2006, when I arrived at the FDA and assessed that information technology infrastructure, we were dealing with a wide diversity of servers or equipment. Much of it had an average age of more than 8 years and was only working at about 30 percent efficiency. We rapidly began to reform and rejuvenate this information technology infrastructure, and you can already see by this year in 2008, we have made progress in streamlining the system, replacing antiquated equipment and improving the efficiency and our targeted and projected by virtue of the information technology plan that we have put in place to be able to totally modernize that system within the next two years. The work has begun but the work is not finished. We have much that needs to be done and this report will be an important contribution as FDA continues on that trajectory, not only in information technology but all the other elements of our scientific portfolio.

Let me be frank, Mr. Chairman. I am here today to testify to Congress and the American people that we should be proud of the performance of FDA as it remains the world's gold standard as a regulatory agency but more importantly, I am here today to work together with you to address the challenges that we face and how important it is to continue to make this agency even greater and able to respond to the rapidly changing world around us. We are

not here today because of what is wrong with the FDA but what is right and must get even better. There are nearly 10,000 individuals in that agency who serve the public every day and the caliber and quality of our current scientists is unparalleled and the commitment of our workforce is truly amazing. Every day these public servants work to protect the American people, whether it is preventing botulism in canned food or evaluating medical devices that are saving lives. Each and every employee is serving this country well, and I assure you, Mr. Chairman and the public, that the FDA employees are as committed as you to continuously improving this agency. It has become the world's standard because of our science and we are here to work together to determine how best to continue that proud tradition.

The American people are blessed and grateful for the fact that their FDA has the world's finest scientists with this unparalleled track record and we need to continue to assure that they have the tools of modern science and technology available to them to continue that record of accomplishment, to expand their size and skills of that workforce and to be certain that they have state-of-the-art laboratories whether it is in the field or currently in development at our facility on the White Oak campus, and I am happy to be here today to discuss the plans that we have to achieve the mutually important goal that you have laid out for us. Thank you, Mr. Chairman.

[The prepared statement of Dr. von Eschenbach follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

ANDREW C. von ESCHENBACH, M.D.

COMMISSIONER OF FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

U.S. HOUSE OF REPRESENTATIVES

JANUARY 29, 2008

For Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs at the United States Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to discuss the important issues relating to the role and support of science at FDA.

On December 3, 2007, the FDA Science Board (Science Board) accepted the report of its Subcommittee on Science and Technology (Subcommittee) entitled, "FDA Science and Mission at Risk." The Subcommittee report reveals a number of areas that recommend increased investment. FDA takes this report seriously. The need to improve science at FDA is not in question. Nor is there any question that we must make a significant investment in improving the science. The hard question we must now answer is how to prioritize the investments needed in the Agency's regulatory science infrastructure.

In my testimony today, I will first outline FDA's request for the Science Board report and the additional work underway. I will next describe the Agency's current and future challenges. I will then discuss our efforts to take inventory and solicit advice, both internally and externally, and our steps to change our practices to address these challenges.

FDA's CHARGE TO THE SCIENCE BOARD

The FDA Science Board is a Federal advisory committee that advises the Commissioner in discharging responsibilities as they relate to addressing specific and technically complex

scientific issues of regulatory importance to FDA. The Science Board consists of a group of senior scientists with accomplished backgrounds in evolving areas of science. FDA Science Board members provide advice and interact with FDA, industry, academia, and other government agencies on technically complicated issues of regulatory importance In December 2006, I asked the Science Board to assess whether science and technology at the FDA can support current and future regulatory needs. The Science Board Chair created the Subcommittee to work on this review. Specifically, the Subcommittee's charge was to identify the broad categories of scientific and technologic capacities that FDA needs to fully support its core regulatory functions and decision-making throughout the product life cycle, today and during the next decade.

The Subcommittee, composed of three Science Board members and other external experts, presented their draft report at the December 3, 2007, Science Board meeting. The Science Board accepted the subcommittee draft report and also requested the following additional work:

- A four page Executive Summary of the report;
- FDA leadership's response to the report;
- Public comments on the report (Public Docket opened January 4, 2008);
- A review of the Office of Regulatory Affairs;
- Further review of the National Center for Toxicological Research; and
- A review of priority science topics and emerging areas of science.

We have taken critical steps to begin to develop, articulate, and execute a well-designed plan for moving forward once the review of FDA science is complete.

FDA—MODERNIZING THE AGENCY

For the past century, FDA has been recognized and praised as the gold standard of regulation of food, feed, and medical products throughout the world. In this first 100 years, FDA used science in the acquisition of data that were subject to statistical analysis as a basis for making decisions. Some of that science was developed within FDA, while a large part was derived from the product of efforts and discoveries in the scientific community. As we embark on the next 100 years, FDA must be more than science-based—it must be science-led. The discoveries occurring as a result of scientific exploration must point the way to FDA's next challenges. The Agency must be equipped with the expertise and infrastructure to meet emerging challenges, such as: foodborne disease outbreaks, whether intentional or unintentional; evaluation of complex drugs and biologics developed by emerging techniques in molecular and cell biology; the potential for pandemic influenza or other emerging infectious diseases; and miniaturized bioengineered medical devices. The world is undergoing a rapid expansion of scientific knowledge and globalization that will have dramatic impacts on the industries and products that we regulate. The world is radically changing around us, and so FDA must change.

FDA —SELF ANALYSIS

FDA has taken a number of steps to support our existing scientific regulatory base and to prepare for future challenges through designing and executing activities based on internal, proactive, strategic thinking. More recently, Secretary Leavitt announced a comprehensive Import Safety Action Plan designed to bolster efforts to better protect the nation from unsafe imported

products. At the same time, the Administration announced the Food Protection Plan which proposes the use of science and a risk-based approach to ensure the safety of domestic and imported foods eaten by American consumers. The plans propose a strategy focused on a risk-based prevention with verification model that allocates import safety resources based on risk.

One recent example illustrates both FDA's application of state-of-the-art applied science, and the Agency's commitment to request peer review and assessment of our work. As part of the Agency's response to the 2007 melamine contamination of animal food, FDA prepared a Multi-Center Melamine Safety Risk Assessment to describe the possible risk to human health associated with eating pork, chicken, fish and eggs from animals that had been inadvertently fed animal feed that may have been adulterated with melamine and its analogues (cyanuric acid, ammelide and ammeline). Just a few months ago, the Science Board's peer-review of the Melamine Safety Risk Assessment yielded general and unanimous consensus that the conclusions of the Safety Risk Assessment were sound and appropriate. The Science Board also found that the collaborative relationship among the Agency participants was an excellent model for other government programs.

FDA has also undertaken many internal reviews at the Center, Office, and Program levels with the goal of ensuring the highest standards of excellence at the Agency. As one example, the Center for Biologics Evaluation and Research (CBER) identified key areas of research needed to facilitate development of safe and effective products in the areas of blood and blood products, vaccines, and cellular, tissues, and gene therapies. These CBER priorities are aligned with FDA and HHS priorities, such as counter-bioterrorism and pandemic influenza preparedness.

External Input

As the Subcommittee noted in its report, the exponential rate of change in science and technology requires FDA to be willing to initiate and continue these diverse self-assessments of the state of science at FDA. But we must also look outside the Agency to benefit from broader expertise. FDA does this in a number of ways. In 2005, the Agency asked the Institute of Medicine (IOM) to study the effectiveness of the U.S. drug safety system, with an emphasis on the post-marketing phase, and to assess what additional steps FDA could take to learn more about the side effects of drugs as they are actually used in the real world of post-market approval. In September 2006, the IOM released its report entitled, *The Future of Drug Safety — Promoting and Protecting the Health of the Public.* The report recognized the progress and reform already initiated by the Agency and made a number of recommendations for additional improvements. Shortly thereafter, in January 2007, the Agency gave its response to the IOM recommendations. We are working diligently on a number of initiatives for improving drug safety that we identified in our January 2007 response to the IOM recommendations, and have already made significant progress on several projects.

ADAPTING TO THE CHANGING WORLD

These internal and external reviews are stimulating change. I have asked for this input—and I am using it. These reviews help assess our activities as well as confirm the changes in the world around us, changes to which we must respond. Let me briefly mention some of our ongoing work.

Nanotechnology Task Force

Recognizing the potential for nanoengineered materials to be incorporated into almost all products FDA regulates, I asked FDA staff to create and implement a focused group of FDA experts: the Nanotechnology Task Force. The Task Force Report, a landmark document for regulatory agencies around the world, was issued in July 2007. The Report provides an analysis of the state of the science as related to FDA regulated products and nanoparticles, an analysis and recommendations for science issues, and an analysis and recommendations for regulatory policy issues. To address the information needs and the differences in regulatory authority, the Task Force has recommended a number of activities to address these challenges, and these will be the subject of public announcements in the future.

Critical Path Initiative

In 2004, FDA advanced the idea of focusing on the critical path that medical products must travel, from the earliest stages of development to their use in patients. The Critical Path Initiative is FDA's endeavor to stimulate and facilitate a national effort to modernize the regulatory sciences through which FDA-regulated products are developed, evaluated, and manufactured. The goal of the Critical Path Initiative is to facilitate projects and initiatives that will help move the regulatory sciences into the 21st Century, enabling us to capitalize on the breakthroughs of basic science. For example, our growing understanding of the role of genetics in medical product development is helping us make personalized medicine a reality.

In another area, new bioinformatics approaches are enhancing the interoperability of information tracking systems in the healthcare environment for all regulated products (e.g., adverse event reporting).

Information Technology

As observed in the report from the Subcommittee to the Science Board, information technology is an important cornerstone of Agency activity. Last year, I hired a new Chief Information Officer (CIO) with experience in developing and managing innovative and cost effective multi-organizational scientific and business programs, re-engineering governmental processes and managing the reduction of duplicative systems. The CIO's position was elevated to include centralized management of all previously decentralized IT services in Centers and Offices. This centralized approach provides the CIO the authority and oversight of available IT resources to meet the challenges of the FDA in the 21st Century. Coupled with resource planning and development activities, the Office of Information Management has undertaken detailed succession planning to ensure that the IT organization that FDA is building for the 21st Century remains reliable in support of FDA's mission and sufficiently flexible to accommodate the science and technology advances of the future.

The formation of FDA's Bioinformatics Board (BiB) in 2006 provided an important means of ensuring that business needs and public safety endeavors are equally met by Agency IT services. The BiB oversees the quality and performance of information systems, including business decisions on prioritization, planning, and execution of Agency cross-cutting business automation projects, positioning the Agency to meet external demands on the Agency while, at the same time, satisfying the needs of FDA programs.

Supporting Collaboration, Strengthening our Workforce

As noted at the December meeting of the Science Board, the ongoing relocation of our employees to the White Oak campus in Silver Spring, Maryland, is essential to fulfill the promise of a strong FDA. FDA will eventually consolidate nearly 8,000 employees, currently located in 20 different locations across the Washington, D.C. metropolitan region, into new, state-of-the-art facilities. The facilities on the White Oak campus are already providing critical scientific capacity—scientists working in modern laboratories with access to the latest technologies and tools—to execute mission-critical responsibilities.

The Path Forward

As I have discussed this morning, FDA faces a number of challenges. Assessments and actions are making a difference. The Agency takes the Subcommittee's assessment of the current and future science and technology needs very seriously and looks forward to receiving the report of the Science Board. We will conduct a thorough and substantive review of the report's findings and recommendations when we receive it.

As I noted earlier, we have taken critical steps to begin to develop, articulate, and execute a well-designed plan for moving forward once the Science Board has completed its review of FDA science. We look forward to the results of the current ongoing work to complete the comprehensive science overview.

CONCLUSION

FDA is keenly aware that we must develop comprehensive solutions to face an ever-changing scientific and technological landscape. We look forward to working with Congress and other stakeholders to strengthen the scientific base at FDA and ensure that in the next 100 years, FDA retains its reputation and preeminence as the gold standard through the use of cutting edge science and technology. We will continue to provide consumers with the safest products in the world. I look forward to a dialogue and partnership with Congress and other stakeholders. Thank you for the opportunity to testify, and I am happy to answer questions you may have.

Mr. STUPAK. Thank you, Commissioner. I thank the Science Board, and I hope the questions and comments by the members up here show the deep respect we do have for the FDA and its employees. There is no doubt that some of the problems we see facing the FDA is not just the FDA's own creation. All of us up here also share some of that responsibility, and sometimes we express that frustration. It should not reflect our deep respect for those employees who work day in and day out for the FDA.

Dr. VON ESCHENBACH. Thank you, Mr. Chairman.

Mr. STUPAK. The Science Board report, I take it you have read it?

Dr. VON ESCHENBACH. Yes, sir.

Mr. STUPAK. What were one or two things that were most surprising to you with that Science Board report? And by the way, thanks for putting together Science Board. I did say in my opening it was you that put it together in 2006 and we do appreciate that, and I have more questions about that but go ahead. What were one or two things you found most surprising about this report?

Dr. VON ESCHENBACH. Well, sir, let me be candid and tell you that I didn't generally find things that were surprising about the report. I did appreciate the very significant emphasis that the report placed and the appreciation that they were able to develop about the importance and insight into many of our scientific needs. I would tell you that for example, their attention to the importance of information technologies and that infrastructure and that would be required to support our endeavor was an extremely important contribution. Their ability to lay out the scientific portfolio that helped us to be able to define and address new trajectories of science including, for example, references to nanotechnology and to systems biology, for example.

Mr. STUPAK. Well, let me ask you this. On page 6 of the Science Board report, and it has been quoted earlier, it says because the agency lacks resources in many key areas that lives are now at risk, and I quote directly from the Science Board: "In contrast to previous reviews that warned crisis would arise if funding issues were not addressed, recent events and our findings indicate that some of the crises are now realities and American lives are at risk." You didn't find that surprising?

Dr. VON ESCHENBACH. No, sir, because I think that is consistent with all of the things that I have been stating and addressing and attempting to approach. We have recognized the world has radically changed around us. We are recognizing that we have to change within FDA to be able to adapt to the challenges.

Mr. STUPAK. One of things to help you change will be resources. When you were at the Cancer Institute, did you not have a budget other than the administration's budget that was, what, a bypass budget?

Dr. VON ESCHENBACH. Congress in 1971 would have passed the National Cancer Act providing unique authorities for the National Cancer Institute to have the opportunity to present a budget directly to Congress.

Mr. STUPAK. Is that a bypass budget or a professional budget, I think was another word we heard?

Dr. VON ESCHENBACH. Euphemistically referred to as a bypass budget.

Mr. STUPAK. Has there been anything like a bypass budget or anything similar to that at the FDA?

Dr. VON ESCHENBACH. I am not aware of that being available to any other agency within NIH or to the FDA.

Mr. STUPAK. Well, you heard Mr. Hutt's testimony about how you have a hollow government syndrome here, that in the next 2 years there should be 50 percent more employees over 2 years at the FDA, double the funding for 2 straight years then maintain a 5.8 percent yearly budget. Do you agree with that?

Dr. VON ESCHENBACH. I agree that the FDA needs additional resources. I have asked for those additional resources as I came to FDA. I think what I have continuously stated has been, it is first and foremost to define what needs to be done. That is why I asked for this report. Once we have defined that——

Mr. STUPAK. But do you agree with Mr. Hutt?

Dr. VON ESCHENBACH [continuing]. Create the business plan.

Mr. STUPAK. But do you agree with Mr. Hutt's estimations what you need?

Dr. VON ESCHENBACH. I cannot agree with Mr. Hutt's estimations because they are just that, estimations.

Mr. STUPAK. OK. Then what——

Dr. VON ESCHENBACH. I need to be able to bring forward an appropriate investment strategy that would——

Mr. STUPAK. What is your investment strategy then for the 2009 budget?

Dr. VON ESCHENBACH. That will be presented by the President next week.

Mr. STUPAK. OK. But what is your recommendation? You said you have made recommendations. What was your recommendation to the OMB, Office of Management and Budget, to Mr. Nussel for the FDA to improve resources?

Dr. VON ESCHENBACH. My involvement was to present to the Secretary——

Mr. STUPAK. OK, Secretary Leavitt.

Dr. VON ESCHENBACH [Continuing]. Request for additional resources.

Mr. STUPAK. OK. Did you request additional resources?

Dr. VON ESCHENBACH. Yes, sir, I did.

Mr. STUPAK. How much?

Dr. VON ESCHENBACH. That will be presented in the President's budget.

Mr. STUPAK. So you don't want to tell us?

Dr. VON ESCHENBACH. It is the purpose of the President to present his budget next week.

Mr. STUPAK. Oh, sure, and the President may agree or not agree with you so we would like to have a yardstick, a baseline to measure by. Did he accept your numbers or did he go lesser or more?

Dr. VON ESCHENBACH. I will along with you await the President's declaration of his budget.

Mr. STUPAK. I don't have the President here so I guess I have to ask you. What is the amount you——

Dr. VON ESCHENBACH. I don't have the President here either, sir. When he is presenting his budget——

Mr. STUPAK. So you are not allowed to testify what your request is?

Dr. VON ESCHENBACH. I am not in a position to testify today to the President's budget.

Mr. STUPAK. Why aren't you in a position to testify?

Dr. VON ESCHENBACH. Because he hasn't released it yet.

Mr. STUPAK. So you are not allowed to say anything until the President releases his budget?

Dr. VON ESCHENBACH. After he releases the budget, we can speak to the budget.

Mr. STUPAK. So then you will come back then in 60 days and talk about his budget?

Dr. VON ESCHENBACH. I will be happy to come back in 60 days once the budget is released.

Mr. STUPAK. Will you come back in 60 days to talk about implementation and what you have done to implement the Science Board's recommendations?

Dr. VON ESCHENBACH. Yes, sir, I look forward to that and I would also even at this point assure you that we have been consistently working to both implement many of the things that the report surfaced as important agendas for FDA and in addition to that following the report's presentation to the last meeting of the Scientific Advisory Board and that report became public, I disseminated that report within the agency and have asked each of our center directors to directly respond to the recommendations in that report and bring forward their operational plans. Many of those things are already underway.

Mr. STUPAK. Great.

Dr. VON ESCHENBACH. And I would be happy to come back and report——

Mr. STUPAK. Is 60 days enough time?

Dr. VON ESCHENBACH. In 60 days I will be able to report to you progress and I will look forward to continuously reporting progress. This is not going to get fixed, Mr. Chairman, within one intervention.

Mr. STUPAK. Oh, I know that.

Dr. VON ESCHENBACH. It will be an ongoing effort with ongoing investment in the resources that it is going to take. It is not a 1-year budget solution and it is not a plan that can be accomplished in 1 year.

Mr. STUPAK. Right. And you know me. I will follow through. This is I think our fifth hearing with the FDA and I expect at least five more before the end of the year. Since I have to ask Secretary Leavitt when he comes about the budget and I know he is coming in a couple weeks to talk about the whole of the HHS budget, we will ask about FDA.

Let me ask you this and then I will turn it over to Mr. Shimkus for questions. Are you pleased with what the President will be presenting in his budget for the FDA?

Dr. VON ESCHENBACH. Well, when the budget is released by the President, then I will be in a position to be able to comment.

Mr. STUPAK. So you can't determine if you are pleased or unpleased until it is released?

Dr. VON ESCHENBACH. Not until the President releases the budget.

Mr. STUPAK. You guys got to lighten up. OK.

Next for you.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Dr. von Eschenbach, thanks for coming. You became the head December 13, 2006. I really do applaud those political appointees who answer the call to serve in the final cycles of an Administration. We saw a lot of people leave in the last year, the last 2 years to do other things. Thank you for serving because government service is not all it is cracked up to be. It is very difficult and very demanding and I do appreciate it, and thank you. As director of the National Cancer Institute, a nationally recognized—I can't pronounce it. I am an infantryman, you are a Navy guy. Infantrymen, we don't go past two-syllable words. So urologic oncologist and a cancer survivor listed in the Best Doctors in America publication, and again, a lieutenant commander in the United States Navy Medical Corps. So you come with a great background of service as a practicing physician but also as you move up the ladder you get involved in major medical institutions and the management aspects. I wrote down in listening to the question, I really have—we of all people, I don't—we never have anybody who comes to Washington, D.C., asking for less money. We never do. And I don't know of a single scientist who would ever tell anyone I want less money, because the more money they have, the more science and the more research they can do. It is just a fact of life. And then we have the budgetary authorization battles and the appropriation battles. We have been trying to focus on management and things that we can do. You were starting to talk about change and adapt. Are there some change-and-adapt issues with the Science Board that you can or already have started implementing that creates quality assurance and efficiencies that you would like to bring out?

Dr. VON ESCHENBACH. Absolutely, Mr. Shimkus. I think it is extremely important for me as, if you will, the CEO of the Food and Drug Administration, to reflect to Congress and the American people that it is not just how much money we spend but how we spend it, and there are extremely important management issues which need to be addressed at FDA in addition to the resource issues, and I have been attempting to respond to both of those challenges. One of those things I did was to bring a highly skilled, highly reputable chief operating officer, which is in fact consistent with many of the reports and recommendations you have heard today. That chief operating officer has gone through a very systematic process of us being able to create better administrative and management infrastructure.

Let me talk about that specifically with regard to then the hiring of a chief information officer. We have heard that FDA has had many chief information officers in the past but under this new system we brought a chief information officer in who was not only highly skilled but we empowered him to be able to start an integrative process across the agency which would create the interoperability that is necessary if we are going to have the right kind of

data systems and databases with which to extract information that we can make intelligent regulatory decisions with. What you saw in that display I put up initially was what was inherited in 2006 was a highly decentralized system where individuals were buying servers and infrastructure for very specific needs and they were only running at 30 percent efficiency. They were spending over $200 million a year just to maintain what had already become antiquated equipment, and it wasn't an issue of how much money do we need to spend in IT, we needed to spend more and we have spent more, but how can we spend it even better, and that is what you are beginning to see in that trajectory, that even within 2 years we have made great progress in beginning to create an entirely new IT infrastructure.

But we didn't stop there. We brought everyone together in terms of what we now call the Bioinformatics Board, which is co-chaired not only by our chief operating officer but most importantly by our chief medical officer, to really ask the question, what are the right programs that need to be running on that IT infrastructure so that we will accomplish mission. And one of the things that we have been working on in that regard that is indirectly aligned with Congress's issues and concerns around the implementation of the Food and Drug Administration Amendments Act is what we would call sentinel network, and this provides us the information or technology infrastructure and programs that we will be able to do postmarket surveillance, which I know is an issue of great importance to this committee.

Mr. SHIMKUS. Thank you, Mr. Chairman, and I yield back.

Mr. STUPAK. Thank you, Mr. Shimkus.

Mr. Dingell for questions, please. Mr. Shimkus is finished.

Mr. DINGELL. Mr. Chairman, I am happy to defer to Mr. Shimkus first.

Mr. STUPAK. He already had his questions and now he is deferring to you.

Mr. DINGELL. Very well. I want to thank you, Mr. Shimkus, and I thank you, Mr. Chairman. First of all, Mr. Chairman, I ask unanimous consent that the record be kept open to include a letter from me to Dr. von Eschenbach and his response to us.

Doctor, welcome to the committee. We have a list here of items which the Science Board makes report to you and quite frankly, it indicates that FDA has very little capacity to carry out its mission. We will submit a letter to you asking how much it will cost each of these items to be fixed and what you intend to do about each of these. Now, the Science Board had an interesting remark to make. On page 21 it says, "During the past 35 years a decrease in funding for inspection of our food supply has forced FDA to impose a 78 percent reduction on food inspections at a time when the industry has been rapidly expanding and food importation has exponentially increased. FDA estimates that at most it inspects food manufacturers once every 10 years and cosmetic manufacturers even less frequently." Is that true?

Dr. VON ESCHENBACH. It is true, sir, that we need to improve our——

Mr. DINGELL. Thank you. Now, Doctor, I note that FDA inspection of foreign and domestic food establishments is referred. In the

table it says that FDA conducted 35,000 foreign and domestic establishment inspections in 1973. By 2006 this number had fallen to 7,783. In recent investigations by this subcommittee, your staff told ours that the volume of imports is doubling every 5 years. Is that true?

Dr. VON ESCHENBACH. The imports are doubling and our foreign inspections are increasing as well, sir.

Mr. DINGELL. It is true. Now, Doctor, the Science Board report suggests addressing food safety issues will cause upwards of at least $250 million. Do you agree or disagree with that statement?

Dr. VON ESCHENBACH. Mr. Chairman, I believe that it is going to require an investment over time for us to be able to continue to implement our food protection plan which we presented. I have requested additional funds for this and have applied funds in 2008 and will be applying funds in 2009 in a continuous trajectory.

Mr. DINGELL. Now, Doctor, the Science Board again says, "FDA does not have the capacity to ensure safety of food for the Nation." Is this a true statement or not?

Dr. VON ESCHENBACH. No, sir, I don't believe that is true.

Mr. DINGELL. You don't believe it is a true statement? You disagree?

Dr. VON ESCHENBACH. I believe we are assuring the food safety.

Mr. DINGELL. Let me quote it again. It says, "does not have the capacity to ensure the safety of food for the Nation." Do you agree with that statement or not?

Dr. VON ESCHENBACH. No, sir.

Mr. DINGELL. You don't agree.

Dr. VON ESCHENBACH. I believe that we need to continuously expand and improve our capability to respond to the changes that are occurring in our food supply.

Mr. DINGELL. You admit the huge decline in the number of inspections made both of domestic producers, manufacturers and processors and of foreign processors and that goes across food, drugs and cosmetics. Is that not true?

Dr. VON ESCHENBACH. Yes, sir. I believe——

Mr. DINGELL. Very good.

Dr. VON ESCHENBACH [continuing]. We need to increase foreign inspections.

Mr. DINGELL. Now, the finding, it says this, "Recommendations of excellent FDA reviews are seldom followed." This is page 56. Do you agree with that finding or not?

Dr. VON ESCHENBACH. Sir, under my opportunity to lead this agency, I have asked for external reviews and I have responded to this external reviews including the Institute of Medicine report, including our ability to bring forward——

Mr. DINGELL. Doctor, is the statement true or not?

Dr. VON ESCHENBACH. I can only speak to my experience, sir. In my experience, I have——

Mr. DINGELL. So you are telling me that the statement is not true?

Dr. VON ESCHENBACH. I cannot——

Mr. DINGELL. You are going to get some mail on this so you better answer this question carefully.

Dr. VON ESCHENBACH. Well, I appreciate the question, Mr. Chairman, but I am attempting to respond to it in the context of my experience at FDA, not that of my predecessors.

Mr. DINGELL. They come forward, Doctor, with another finding. "FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak," page 3. Do you agree with that statement or not?

Dr. VON ESCHENBACH. No, sir. I believe the scientific base of the FDA is strong but it needs to be stronger to respond to the emerging challenges and changes that are occurring in the world in science and technology and in the products that we are called upon to regulate. So it is not that it is bad, Mr. Chairman. It is that it is at a level of excellence that needs to continue to improve and continue to expand.

Mr. DINGELL. Now, I understand that you have not been allowed to comment on the Science Board report, suggesting that addressing food safety issues will cost up to $250 million. Given that, I am curious. How can GAO expect to get the numbers on these matters either from you or the Administration?

Dr. VON ESCHENBACH. Well, Mr. Chairman, there is nothing that says I have been told I cannot comment. What I have tried to express very carefully is that it is important to define what needs to be done and how that process can be carried out——

Mr. DINGELL. Well, let us——

Dr. VON ESCHENBACH [continuing]. And then assign a cost to that.

Mr. DINGELL. Let us end the remaining time which I have and have you tell us how much will be the amount of money which you will require to carry this out properly.

Dr. VON ESCHENBACH. Mr. Chairman, what I am attempting to do is to create a plan which I have promulgated, the Food Protection Plan, which has both authorities that are going to be required from Congress as well as programs that are going to require additional appropriations. We will build the business plan as to what the cost of those investments will be and their source. Some of it will come from appropriations, some of it will come from user fees——

Mr. DINGELL. Let me raise one last question. Regarding your IT system, they made some very adverse comments on your operations in disaster recovery plan having no continuity in your agency's IT system. Were you surprised by that finding, yes or no?

Dr. VON ESCHENBACH. No, sir——

Mr. DINGELL. Why not?

Dr. VON ESCHENBACH [continuing]. And we are in the process of addressing that and remedying that.

Mr. DINGELL. Now, Doctor, then on page 5 the report notes that FDA has inadequate emergency backup systems in place and recent system failures have resulted in loss of FDA data. Is that true?

Dr. VON ESCHENBACH. Yes, sir, and we are continuously remodeling——

Mr. DINGELL. And it also——

Dr. VON ESCHENBACH [continuing]. And improving that.

Mr. DINGELL. It also says that there is no backup of these records which include invaluable clinical trial data. Is that true?

Dr. VON ESCHENBACH. The records that we have been receiving and previously have been primarily in paper form and we need to transition to——

Mr. DINGELL. The answer really to the question I ask is yes or no, is there backup or is there not?

Dr. VON ESCHENBACH. There needs to be better backup.

Mr. DINGELL. Thank you.

Mr. Chairman, I have used your time. Thank you.

Mr. STUPAK. Thank you, Mr. Dingell. Mr. Barton for questions, please.

Mr. BARTON. Thank you, Mr. Chairman.

Thank you, Dr. von Eschenbach. I have been watching the hearing on television as I have scurried before the three subcommittees that are in action at one time. Mr. Dingell is setting a record for number of subcommittees meeting concurrently and it makes it hard for he and I both to be all three places.

Let me start out by asking about the genesis of this subcommittee report. How did that come about, the report that we are reviewing today? Who originated or asked that report be done?

Dr. VON ESCHENBACH. I did, sir.

Mr. BARTON. You did? So this is something that you asked for?

Dr. VON ESCHENBACH. Yes, sir.

Mr. BARTON. Were you forced to ask for it or——

Dr. VON ESCHENBACH. No, sir.

Mr. BARTON. You did it of your own initiative?

Dr. VON ESCHENBACH. Yes, sir.

Mr. BARTON. Now, would you have been surprised if this subcommittee had reported back that everything was just hunky-dory and pink and rosy and they had more money and people and systems were operating at 100 percent efficiency and they were really insulted that you asked them to waste their time doing this report? Would that have surprised you if they had given you that kind of——

Dr. VON ESCHENBACH. Shock might be a better term.

Mr. BARTON. So it is not a surprise that you have asked this subcommittee to do a thorough analysis of the FDA and how it can be improved and what its shortfalls were and, and lo and behold, they gave you such a report. That is kind of what you expected, isn't it?

Dr. VON ESCHENBACH. Yes, sir, and I think it is important for me to again compliment the committee because the fact of the matter is, I have recognized as having been part of the world that created many of the opportunities that are now available to us to save lives and to improve the health and welfare of the American people the gateway or the bridge from all that discovery and that development whether it is nutrition or whether it is drugs that are going to eliminate suffering and death due to cancer, none of that is going to be reach the American people unless it goes through the FDA, and the FDA must be the bridge and not the barrier to that new future, and FDA's ability to do that is based on its science. It has always been a science-based regulatory agency and I perceive it needs to be also a science-led regulatory agency, and first and foremost with the question to look at our scientific portfolio and ask

experts who have that understanding and perspective of that full continuum of discovery, development and delivery to look at that portfolio and advise me as to where that portfolio needs to be modified, where there were gaps, where there was overlap, and even more importantly, where there were opportunities to leverage that portfolio with science and technology that was occurring in other areas like the NIH where $28 billion has been invested in science and in industry and other places and they did an extraordinary job and a service to the agency to come forward with the report that——

Mr. BARTON. Now that you have this report, have you put it on the shelf and said well, good, I have it——

Dr. VON ESCHENBACH. No, sir. I think my track record affirms the fact that I asked for reports and accept reports and then go about the process of working with the agency to properly implement those——

Mr. BARTON. So you are interactive with the committee and you are meeting with them and your associates at the FDA are meeting with them to prioritize an action plan and develop it. Is that——

Dr. VON ESCHENBACH. Well, it is important to point out that the Scientific Advisory Board has been in place since the 1990s. They have been charged by charter to have responsibility to advise the FDA with regard to its scientific portfolio.

Mr. BARTON. Would you hope that this committee would work with you and your agency and develop a bipartisan plan of action where we could give you additional funding in high-priority areas and actually put something before the Congress and the President at the appropriate time that, you know, here is where we need more resources and here is how we plan to spend the money and here is the technology. Would that be something you hope the committee does or do you want us just to yell at you and point fingers and try to do gotcha stuff?

Dr. VON ESCHENBACH. Mr. Barton, I have enormous respect for this committee and I think from the time I have engaged with the committee and its staff, I would look forward to every opportunity to work together so that we can create the right plan and——

Mr. BARTON. It is obvious——

Dr. VON ESCHENBACH [continuing]. Implement it in the right way in service to the American people. That is what we are both here for.

Mr. BARTON. The task force has shown some real areas that need to be improved and I think Chairman Dingell pointed some of that out. So our job is to figure out what we need to do and the best way to give you the resources and if necessary make statutory changes in terms of structure so that the FDA can be the best that I can be.

Dr. VON ESCHENBACH. And if I can comment on that, Mr. Chairman. For example, we have already issued our Food Protection Plan, which is along the lines of being able to accomplish what you just said. In that plan, there are requests for authorities that the FDA doesn't currently have. Those are specific issues for this committee and we look forward to working with you on those authorities.

Mr. BARTON. My time has expired, and I am on regular time. I am not on chairman time so I need to—just one final thing. When Chairman Stupak was asking about your budget submission to the President, you had declined to answer for the simple fact that the President's budget has not been made public, and that is kind of traditional practice that Cabinet agencies and commissioners don't get out ahead of the President, let him offer the budget and then you can come up here and comment on it and at the appropriate time. You will be happy to do that. Isn't that correct?

Dr. VON ESCHENBACH. Correct, sir.

Mr. BARTON. So you weren't being mean to Chairman Stupak, you are just not allowed to comment until the President's budget comes out, and if it were a Democratic President, a Democratic-appointed Commissioner, it would be the same thing. Isn't that true?

Dr. VON ESCHENBACH. That is correct, sir.

Mr. BARTON. Thank you.

Mr. STUPAK. Democrat or Republican, I would ask the same thing. You could at least tell us if you were pleased with the recommendation without giving a number.

With that, let me go to Mr. Inslee. I think you were next.

Mr. INSLEE. Thank you.

Doctor, I want to ask you about these electric energy devices you may have heard me talking about in my opening statement.

Dr. VON ESCHENBACH. Yes, sir.

Mr. INSLEE. And I want to just take this one case as illustrative of what may be in the realm of the possible. I told the story about a fellow who actually had a device that was subject to false claims. USDA shut them down. He refused to stop selling it. He actually left the country. I am told there is a felony warrant for his arrest. But he is still over in Hungary selling these products and according to an article has sold 10,000 of these in the United States. To me, it is just really flabbergasting that we can have somebody who has been identified as a miscreant who is selling thousands of these without our ability to really stop that, and I wonder if you want to give us your thoughts as to whether that is a failure of our system and if so, what would you identify what needs to be done to solve that?

Dr. VON ESCHENBACH. First of all, when I listened to your story as a urologic oncologist who spent my entire career taking care of cancer patients, I have witnessed how they can be preyed upon by these kinds of fraudulent and false hopes and devices, and I am as committed as you are to a system solution to this problem. I think it is really a systems failure and a systems solution, that first and foremost we need stop this at the source. Now, FDA has been working with foreign regulators, our counterparts in these other countries, so that they can take appropriate action. Now, obviously there is some heterogeneity, depending upon which country you may be interacting with, but I want to assure you and the committee that we are going right to those foreign sources to get them to intervene. Number 2, we have put an import alert in place for this specific product so that we can alert the borders to stop those products at the border, whether it is, you know, customs and border protection or whomever but we will stop those at the border. Clearly some of those get through and we need to improve that as

well and then once they are here we have to detect them, and local authorities have the jurisdiction and the authority, since we have taken action against that product, to eliminate it and prosecute anyone who is marketing is under those false claims that you alluded to that it would cure their cancer. So I think we have steps but clearly there are times when those steps are not sufficient, and that is why in our strategy I talk about being engaged in the total life cycle of products, I talk about a process that builds in prevention, intervention and response as a continuum and in that way really attempt to really protect and promote the health of the American people.

Mr. INSLEE. Sometimes bold action can help in this regard too and send signals. Is there an extradition possibility with this individual, do you know?

Dr. VON ESCHENBACH. I can't tell you about extradition in terms of the specific country that he is in.

Mr. INSLEE. He is in Hungary, I am told in the newspaper.

Dr. VON ESCHENBACH. I don't know enough about the law.

Mr. INSLEE. How would that work? Would you go to the Justice Department and request them to pursue that, or how would that work?

Dr. VON ESCHENBACH. I cannot——

Mr. INSLEE. Or is that just their initiative?

Dr. VON ESCHENBACH. I cannot answer that for you at the present time. I don't know, and I would have to get our legal people to tell me what that step would be. I do know that we have been—in these kinds of cases we work with the local government for them to take action directly.

Mr. INSLEE. May I ask that you pursue that and let me know what the options are? You know, I am just going on what I have read in the newspaper but it would seem to me if that is a legal course of available to the United States, it is a statement that we should make, and I hope you will let me know what your progress is on that.

Dr. VON ESCHENBACH. I would be happy to do that, sir.

Mr. INSLEE. How much of this—we have been talking about resources. How much of this is a resource issue? You heard previous testimony about needing field agents to really track this down and it seems to me pervasive. You look at the Internet and these things are all over the place with sparks and whistles and, you know, obviously these people are blatant out there. They are not trying to hide this. They want to advertise it. How much of this is not having agents in the field to go after these problems?

Dr. VON ESCHENBACH. Well, again, I want to emphasize the fact that I agree that we need to increase our resources, our Field Force, our number of inspectors, but I think it is important to go beyond just looking at the numbers of inspectors and understand how we will address the problem. There never will be enough inspectors. When we look, for example, at the number of foreign facilities that are producing products that we must regulate, we recognize that what we need to do is not just increase the number of FDA inspectors but to increase their effectiveness. One is by doing that on a targeted risk-based approach that they inspect the right things that are of greatest concern. Number 2, that we leverage

their impact, and we have asked, for example, for opportunities for us to have the authority to certify third parties that we could oversee and control but they could do additional inspections, to work with foreign governments where their own infrastructure, their own regulatory processes, their own inspections would be complementary and integrated with ours. We have worked with States here within the confines of the United States where they are doing a significant number of inspections under FDA's direction and with FDA's certification, if you will, and that has significantly leveraged our impact. We may do 7,000 inspections and States have done approximately 8,000, so we are doubling impact but not necessarily doubling the number of FDA inspectors. And I express that because I want the committee to appreciate that I am not looking at this simply from the point of view of if we had this amount of money, we would hire this many more inspectors. I think we have to think more strategically than that, and it is a matter of how can I maximize the effect of the inspectors, not just increase their number.

Mr. INSLEE. Well, we hope you will put the FDA in zap mode on this, and good luck. I would like to help you out. Thank you.

Mr. STUPAK. The gentleman's time has expired. He has asked all day about this EPFX. Why does the FDA even allow them in the country? You allow them in as a stress reliever.

Dr. VON ESCHENBACH. Well, we have an import alert to keep them from coming into the country.

Mr. STUPAK. Pardon?

Dr. VON ESCHENBACH. We don't allow them into the country. Now, that is not to say——

Mr. STUPAK. According to the article, they are a stress reliever. If they are being abused, why would you even let them in?

Dr. VON ESCHENBACH. Mr. Chairman, we do not allow them to come into the country. There is an import alert that they would be stopped and seized at the border. You clearly have indicated——

Mr. STUPAK. Whether they are stress relievers or not, so if they are labeled as stress relievers you are going to seize them? Stress relievers. FDA has licensed them as stress relievers.

Dr. VON ESCHENBACH. If there is a claim made that they would, you know, cure a disease like cancer——

Mr. STUPAK. No, stress.

Dr. VON ESCHENBACH. There are certain products that can be marketed that don't make claims that fall under the Food, Drug and Cosmetic Act and those things are not subject to our regulation based on the law and based on our statutes.

Mr. INSLEE. Mr. Chairman, may I ask for an additional 1 minute?

Mr. STUPAK. Sure.

Mr. INSLEE. You have really brought up an important issue here. What I sense is going on here is that these machines are being—when they come in, they are identified as stress relievers or, you know, some other type of benign nomenclature, and they are being—you are getting through the sieve or the net through that. Then the folks overseas and other places basically advertise them on the Internet and by the providers themselves who tell the patients, who tell the victims this isn't just a stress reliever, it is a cancer reliever, it is an allergy reliever, it is an osteoporosis re-

liever. So the problem is, I think there is this missing part in our net where you get the machine in under this benign nomenclature and then the patient is told that it has all these other miraculous attributes to it, and I think we need to think about how to seize that where basically you have to go say at the border somehow or some other way, if there is anybody else making claims about this machine, you can't put it in, and this is where I think there is a little slip between the licensing and the practitioners and the sales of the machine. Somehow we have got to get on top of this where people are using these machines for nefarious purposes. They know that is going on on a repeated basis and we have to be able to shut those down for import. Does that make sense?

Dr. VON ESCHENBACH. Yes, sir, I understand.

Mr. STUPAK. Mr. Burgess?

Dr. VON ESCHENBACH. I will get you the specific——

Mr. STUPAK. I am sorry. Were you done?

Dr. VON ESCHENBACH. That is OK.

Mr. STUPAK. Mr. Burgess for questions.

Mr. BURGESS. I hate to prolong this agony but, Mr. Chairman, can I just ask you, is there not an ongoing investigation by this Oversight and Investigation Subcommittee on said machines?

Mr. STUPAK. We just started to gather the information.

Mr. BURGESS. So there is an investigation in progress, and honestly, I don't want to devote any more to it but I think both the FDA and the Oversight and Investigation Subcommittee are on the job and this is something that will be correctly elucidated at the proper time.

Commissioner, I just want to thank you for your forbearance and staying with us all day. You have lost well over half a day from your primary job at the agency and I know there is a lot of stuff facing you and it does seem unkind that we have tied you up so long. Let me ask you, you have talked to Ranking Member Barton about your activities vis-a-vis the report. At some point this subcommittee will receive the FDA's formal response to the report that was generated. Is that correct?

Dr. VON ESCHENBACH. Yes, Dr. Burgess. I actually would welcome the chairman's earlier suggestion that there be a subsequent hearing of which I have the opportunity to come back and brief the committee or present to the committee FDA's progress and initiatives that are directly responsive to many of the issues that the report has addressed, so I welcome that. I would do that formally in the context of a hearing. I would be happy to do that informally and simply as it relates to a progress report or whatever the committee wishes. But whether it is to this committee or not, I fully expect to continue to inform the American people and continue to present what FDA's process and progress have been because I am not interested in plans, I am interested in progress and outcomes, and the plans are only to guide me as to how to accomplish those outcomes.

Mr. BURGESS. And just to reiterate the ranking member's point, this was an activity that was initiated by the Commissioner's office. Is that correct?

Dr. VON ESCHENBACH. Yes, sir, absolutely.

Mr. BURGESS. You know, we heard a lot about information technology and the problems that you face with the system you inherited, so presumably that would be one of the top three things that will come out of this activity, and I do want you to talk about that but I would also like to hear just briefly what the other—if we are going to talk about the top three areas as we develop our short-term, mid-term and long-term goals, where those issues lie.

Dr. VON ESCHENBACH. Thank you for referring to that. Let me frame the answer by saying I have assessed the FDA from the first moment I arrived and I came rapidly to the conclusion that the two most critical assets at the FDA were its people and its infrastructure, its tools, IT tools, because essentially we spend 80 cents of every dollar on people and it is in fact what is most critical to FDA's success is to have the right kind of people and sufficient numbers of that. So my first priority was to address the workforce and what was going to be required to nurture and develop that workforce, and you have heard on other occasions about my plan for, for example, a very expanded credentialed, formalized FDA fellowship program as one way of bringing additional intellectual capital into the agency. The other thing that was apparent was that they needed the right tools and information technology tools were the most critical if we were going to do post-market surveillance. If we were simply going to be able to process the data, information that is coming to the FDA in the form of a drug application or by virtue of adverse-events reporting, we needed a modern IT infrastructure. I looked at our IT infrastructure and recognized immediately it needed to be totally, completely revamped if it was going to be adequate for the future challenges that were emerging like post-market surveillance, and we began that process in 2006, and earlier I showed a brief slide to indicate what kind of progress we have made in rebuilding that infrastructure. I would be happy to present to the committee and to others the very detailed plan, implementation plan with milestones and outcomes that our chief information officer has been preparing and we have been implementing, and I am committed as the report indicates is necessary and as the Congress wants and is holding me accountable for to rapidly and radically transfer the information technology infrastructure at FDA.

Mr. BURGESS. Certainly this committee wants to support you in that endeavor. Now, we heard reference a little bit earlier to timelines for the, I think it was the information supply chain. Do you have a sense as to when you will be able to report back to this committee and what you will be able to report back as far as the progress that you are making along those lines?

Dr. VON ESCHENBACH. I would welcome the opportunity to report to the committee on the progress that we have made thus far which I believe is important and substantial and I also would address the timelines and the implementation strategy that we have targeted 2010 to bring the agency to a point where it has the appropriate infrastructure and the right bioinformatics that are operative on that IT infrastructure.

Mr. BURGESS. And too we hear from the National Institutes of Health, Dr. Zerhooni talks about a day that is coming with partialized medicine. It just seems like if the FDA is going to be

able to adequately participate in that new world, that your tools that you are building right now are just going to be absolutely critical to be able to develop that.

Dr. VON ESCHENBACH. And importantly, we are not developing it in a vacuum. First of all, the first principle of our IT infrastructure is the fact that within FDA there will be integration across the centers, and secondly, FDA will be integrated with the components outside of the agency that are critical and essential. So, for example, in our sentinel initiative, we have signed a memorandum of understanding with the Veterans Administration, with the Department of Defense. We have a relationship with Center for Medicare and Medicaid Services with regard to their database. We are engaging with the private sector and private health plans. We have been working through the Brookings Institute to create this nationwide interoperable network that will enable FDA as it catalyzes the development of that network to have access to information about the actual experience of drugs and devices as they are being used in diverse populations so that not only do we immediately begin to detect patterns that reflect an unexpected adverse event, but even more importantly, as physicians we recognize in treating patients there are those times when you recognize unexpected, incredible efficacious events that if you capture that and understand it, you can begin to understand how to use the medicine even better, and I think that is within our grasp and that is something we are going to accomplish but we are going to accomplish it as part of a network, and you have made that possible for me by virtue of the passage of the Food and Drug Amendments Act and we hope to do this through the Reagan-Udall Foundation as we get that up. So I compliment and thank Congress for the opportunity and authority to do that.

Mr. BURGESS. Very good. I will yield back, Mr. Chairman.

Mr. STUPAK. The gentleman's time has expired.

Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman, and like my colleagues, I would like to welcome Dr. von Eschenbach in coming from Houston. You spent it seems like 30 years with M.D. Anderson as both a researcher and a physician. I appreciate it. I also appreciate the job we expect you to do at FDA, although I will tell you my frustration. You heard it from lots of members on a bipartisan basis. When someone is appointed by any administration, and I know we have the same problem in Democratic administrations, you owe your loyalty to that person, in this case President Bush or previously President Clinton, but because of your appointment and confirmation, you also owe it to the American people, and I have had discussion with appointees bipartisanally over the years and there is bound to be, Mr. Chairman, some way where we can draw a line that says the head of a major department like the Food and Drug Administration can tell Congress what their request is because I think we ought to know, and the President would submit the big budget to Congress but I think we ought to know the wish list from the FDA or the wish list for, you know, any other Federal agency, and I guess because in my experience here on the Hill, I have some other former Texas who are in healthcare facilities like yours, and after they left that particular administration, their free-

dom of speech was suddenly restored, and it was nice to be able to say well, at that time I had a different boss, I recognize you have a different boss, and sometimes we do that too. I understand if you are a committee chair in the House, you have a different boss and we always do but it is frustrating because this report raises a lot of concern, and was on the docks at the Port of Houston with FDA inspectors and it was frustrating to find out that, you know, our FDA inspectors are on the docks, we don't have enough of them, and the headquarters is down in Laredo and Laredo may be very good because of the land base, biggest land-based port in the world, I guess, but because of all the foodstuffs that are imported and other things from Mexico. But I think the report shows that we have a problem, and in Texas we would say our ox is in a ditch and we need help getting it out, and I think that is what bipartisanally you are hearing from us because our committee is responsible for that. I wish I could tell you we also appropriate money but that comes from that other committee, and it is frustrating because we want to give you the tools but we also—some of it is so money-based, if you want more inspectors, we have to pay for them. If we want labs to be able to get the results back quicker, then we have to pay for them, and those labs have to be close to the places. The closest lab in Texas FDA has is Arkansas. There is not even one in Texas. Chairman Dingell, I have this discussion about his bill that would require some of these testing. Well, I don't know if we need a lab at the Port of Houston but I know we need ability to contract for testing that may be closer than Arkansas is for all the Texas border.

Let me ask you, in the GAO, typically whether it is FDA or other agencies, FDA had a lot of attention this year with the reauthorization, and I know you mentioned the aftermarket studies and that is now in statute and it is very important that you have the resources to do that in this last year and maybe your predecessor next year will have it, and what the GAO I think is telling us in the findings by the Science Board report as well as GAO working on food safety is, FDA's food inspection program, FDA's foreign medical device inspection program together conclude that your agency is facing considerable resource constraints. Would you agree with that?

Dr. VON ESCHENBACH. Yes, sir.

Mr. GREEN. And last November the GAO testified on the average you were able to inspect foreign manufacturers only about once every 13 years. Is that considered something that the FDA could agree with?

Dr. VON ESCHENBACH. In terms of the manufacturers, I think it is important to point out what kind of manufacturer.

Mr. GREEN. Foreign drug manufacturer.

Dr. VON ESCHENBACH. The overall number is fine.

Mr. GREEN. And in China the data show that your agency at present inspection rates would only be able to inspect each firm every 50 years. Is that——

Dr. VON ESCHENBACH. The way that is arrayed, Mr. Green, let me try to point out that as it relates to, for example, a new drug or new device that is being produced beyond our borders, they all get inspected before that new device or drug is approved. Some of

the inspections that those numbers are referring to are inspections of plants that are already operative and underway for which products are approved and we go back and reinspect, and the point I made earlier and I want to continue to emphasize is that when one looks at the number of places that are now engaged in food production and manufacturing, we cannot simply look at a formulaic number in terms of how many times we inspect each one of them because they are not all the same.

Let me talk about devices in terms of the three classes, which I know was raised earlier by the chairman. Factories that are making tongue depressors for which there is relatively little, if any, risk of that product being problematic even though we regulate it would require a much different frequency of inspection than a factory that is making cardiac defibrillators, for example. So I think the numbers are important overall but it is really important to look beyond the numbers to how we will improve the effectiveness of FDA's regulatory function in a risk-based model that extends our number of investigators and number of inspections to do the right thing in the right way, and I say that because I recognize the numbers are being discussed and I respect the fact we need to do more but I want you to understand I am trying to do more in a better way.

Mr. GREEN. Well, and we want you to do that but we also recognize, and I think on a bipartisan basis, you need to do it in a better way but we also need to have more resources because if I am ingesting medication from some other country and we don't inspect them but maybe every 50 years or 13 years even on the average, it is different than a defibrillator but I watched at that dock where these toys were seized by customs agents but also in some cases counterfeit medication that the FDA inspectors were also to seize, and so that is why I say those inspectors on the docks and at the ports of entry have a very difficult job, and they just need to have reinforcements to do it and I think that is what the GAO report is probably aiming at, and whether it is this current Administration or the next one, this Congress is going to have to make sure that those resources are there.

Dr. VON ESCHENBACH. Yes.

Mr. GREEN. Thank you, Mr. Chairman. I appreciate your patience. I know I am over time.

Mr. STUPAK. Thank you, Mr. Green.

Mr. Walden for questions, please.

Mr. WALDEN. Thank you very much, Mr. Chairman.

Dr. von Eschenbach, thank you for being here today. We appreciate your patience and your input and your leadership. Let me see if I can kind of sum this up since I guess I am at least at this point the last one. You have been there about 2 years as head of the FDA.

Dr. VON ESCHENBACH. Yes, sir.

Mr. WALDEN. When you got there you found there were problems at the FDA that are systemic that go back 2 decades.

Dr. VON ESCHENBACH. Challenges at the FDA that——

Mr. WALDEN. Challenges. All right. Among those are an IT system that is inadequate for the demands of today.

Dr. VON ESCHENBACH. Right.

Mr. WALDEN. Among those is a lack of inspectors to keep pace with the imports that are coming in, especially doing investigations and inspections overseas because of the shift that has occurred in our economy. You have asked for reports from outside and internal entities to tell you what the problems are and provide you with opportunities to solve them, and that is kind of where we are at today. Is that accurate?

Dr. VON ESCHENBACH. Yes, sir. I would like, if I can, to just add that not only have we been identifying these challenges but we have been working towards systemic solutions to those challenges. I have referred often to our IT plan. I looked at initially when I arrived. We were making a $200 million investment in IT. It is up to $247 million. We have looked at the number of inspections and the challenges of increasing the need to be more engaged beyond our borders, and we have increased the number of inspectors and the number of inspections, but the issue here is that is not going to get addressed in 1 year or in 2 years but what I want to do is create a trajectory that continues to keep pace with the challenge.

Mr. WALDEN. Then in terms of trying to keep pace, you have indicated you reached out to do some FDA inspections with outside organizations maybe in foreign countries. Do you have MOUs, memorandums of understanding, with foreign governments, foreign agencies similar to your own to try and get a better handle?

Dr. VON ESCHENBACH. We are in the process of working aggressively to create those relationships with those beyond our borders. Of course, most recently we have addressed the issues having to do with China. We have two memoranda of agreement that we signed with the government agencies within China that are our counterparts. We have been working unilaterally and bilaterally with many nations, and this is a strategy that we will continue to pursue.

Mr. WALDEN. I will just speak for myself but I assume other members of the committee might be interested over time to occasionally get updates on those memoranda and where we stand and the progress you are making on that front. That would be helpful.

The other thing I have heard today is that your agency and that of directors prior to you has sort of over time been asked to do all kinds of new tasks and not necessarily funded to do those jobs. Is that an accurate assessment?

Dr. VON ESCHENBACH. I believe that the report that was presented earlier today by Mr. Hutt reflected the number of additional responsibilities that have been placed on the FDA for which he did not find a revenue stream to support that. I have attempted to look at our resources not only from the point of view of what Congress allocates in the form of budget but what Congress also allows us to acquire with regard to user fees and also now the private foundation, the Reagan-Udall Foundation.

Mr. WALDEN. And I have only got a minute or so left. I want to hit two topics. One is the user fee topic, and it seems to me, given the fight that always occurs up here on the Hill for general fund money, what about this issue of user fees? I know there are those who probably even on the panels that have done investigations that think you don't want to get too cozy with industry if they are funding it, there won't be that sort of separation. There are others who

say your agency doesn't have the resources it needs and, frankly, industry benefits by your stamp of approval.

Dr. VON ESCHENBACH. I mentioned those specifically because the data that Mr. Hutt presented did not incorporate the addition of the user fees and what that has done as far as our ability to increase our workforce. Having said that, we have recognized that with regard to the user fee program, is absolutely essential that we keep them restricted and defined as just that, a fee for service for which the industry deriving a direct and specific benefit——

Mr. WALDEN. Right, helps pay for——

Dr. VON ESCHENBACH. Helps pay——

Mr. WALDEN [continuing]. Regulatory costs——

Dr. VON ESCHENBACH [continuing]. Regulatory costs so it doesn't become a burden for the taxpayer and that also we have an absolute firewall such that that fee does in no way shape or form influence the regulatory decision, and I think if we put those kinds of safeguards in place, Congress holds us accountable, that can be an important component of our overall resource base. I think we have to explore the opportunities for public-private partnerships and the Reagan-Udall Foundation that I hope that we will be able to implement has given us the opportunity to create that because in the public-private opportunity, for example, I alluded to our surveillance network, we have great opportunity to leverage and do what the Science Board report said we should do which is access expertise and resources that are available in other places to do what FDA needs to do.

Mr. WALDEN. The second and final point I would like to throw your way, there are certainly many Americans, certainly members of Congress who think we should open the door for importation of pharmaceutical drugs from foreign countries. We have had votes on that in the House. There is a lot of pressure to do that. Can your agency certify if that were to take effect that the drugs that people would be ordering off the Internet or coming across our border are safe and are actually what they would be thinking they were filling a prescription for?

Dr. VON ESCHENBACH. We are committed to continuously doing everything possible to ensure that the drugs and devices that Americans use are safe and effective, and in looking at the import problem, we have been unable to be certain we could ensure that, even when they are labeled as having come from what we could consider a reputable source like Canada, the product itself often is not and they are often coming from places other than Canada that we have absolutely no control or confidence in or when analyzed found to either not contain the active ingredient or to contain ingredients that are in fact harmful. We have no way of being able to ensure the safety of reimports.

Mr. WALDEN. Thank you, Mr. Chairman.

Thank you, Dr. von Eschenbach. We appreciate your testimony and answers today.

Mr. STUPAK. I thank the gentleman.

Let me ask this question. I asked you earlier about the report. You said you read the Science Review Board report, correct?

Dr. VON ESCHENBACH. Yes, sir.

Mr. STUPAK. And nothing surprised you in that report, correct?

Dr. VON ESCHENBACH. That was my answer, yes, sir.

Mr. STUPAK. But then when Mr. Dingell asked you about the food safety where the report says you cannot provide for food safety of the American people, you disagreed with that.

Dr. VON ESCHENBACH. Yes, sir.

Mr. STUPAK. So the report says we are not doing a good job on food safety, we inspect about 1 percent of all the food that comes in, and you think that is a good job?

Dr. VON ESCHENBACH. Mr. Chairman, let me be specific. I mean, you asked me if I was surprised about something in the report. I am not surprised that someone would have a different opinion than me.

Mr. STUPAK. So you are not surprised that the Science Review Board says we are failing to protect our food supply coming into this country?

Dr. VON ESCHENBACH. I believe the American food supply is among the safest in the world. I believe we must continue——

Mr. STUPAK. So do you disagree with the Science Review Board statement then on food safety?

Dr. VON ESCHENBACH. I disagree that food safety today in the United States is not one of the finest in the world. I believe that to be the case.

Mr. STUPAK. It is not whether it is the finest, whether we are providing the adequate protection the American people expect and the Science Review Board says we are not. Do you disagree with that statement, yes or no?

Dr. VON ESCHENBACH. It is hard for me to say we are not doing it when it is the finest food supply in the world, or among the finest food supply in the world, and when we recognize the nature and complexity of the problem that we need to continuously——

Mr. STUPAK. The food supply, I agree, we have tons of it coming in. Every 5 years it doubles. The Science Review Board says we are not doing a good job. Do you agree or disagree with——

Dr. VON ESCHENBACH. Well, what is the basis for not doing a good job?

Mr. STUPAK. It is all there in the report. We don't have inspectors, it doubles every 2 years. We don't have any IT, all these things. We have had hearings on it which you testified.

Dr. VON ESCHENBACH. Mr. Chairman, I am not saying that there aren't problems and issues with regard to continuously ensuring the quality of our food supply. That is not my point.

Mr. STUPAK. Let me ask you specifically then. It is report of Subcommittee on Science and Technology 3.1.1, finding, "The FDA does not have the capacity to ensure the safety of food for the Nation." Do you agree or disagree with that statement?

Dr. VON ESCHENBACH. It is ensuring the safety of the food supply. We have one of the finest——

Mr. STUPAK. So you disagree with that statement?

Dr. VON ESCHENBACH [continuing]. Food supplies in the world. That is not to say there aren't challenges that I have been——

Mr. STUPAK. They didn't talk about challenges. They said you did not have the capacity, the FDA—and I am not trying to put you on the spot, I am not trying to argue with you. I mean, do you agree or disagree?

Dr. VON ESCHENBACH. I disagree with that.

Mr. STUPAK. OK. In their report, they also talk about personnel morale, and we talked about IT and I believe Dr. Nordenberg said that multiple turnovers as the head of your IT department, like five times in the last couple years, and then you don't have a chief medical officer. The chief medical officer is also the deputy director of the department and Dr. Cassell said that is just way too much for one person, and they do cite the morale problems. What is the systemic problem with the morale problem at the FDA?

Dr. VON ESCHENBACH. Let me kind of address some of these issues specifically, first of all, the turnover of chief information officers. Since I have been at FDA, I have brought in a chief information officer but brought one in with unique and specific expertise but also with a very significant fundamental change in the charge to that chief information officer and their authority and responsibilities. We had chief information officers that were overseeing a totally distributed fragment system with no authority to be able to integrate or centralize that system. The very fact is, I not only got a chief information officer with unique skills and background and experience but enabled and empowered him to make fundamental systemic changes——

Mr. STUPAK. Do you have a plan to implement your IT then? You have a new officer. Do you have a plan to implement it?

Dr. VON ESCHENBACH. Absolutely.

Mr. STUPAK. What is the cost of that plan to implement your new IT?

Dr. VON ESCHENBACH. We have invested at this point incrementally from $200 million when I arrived to now a total of what is $247 million, and I demonstrated that that has been successful at being able to put us on a trajectory to totally continually refurbish that entire infrastructure. So let me try to be clear about the chief information officer turnover. As it relates to the other issues of change in leadership, the director was recruited to be the acting surgeon general of the United States, and that is not—he didn't leave because there was a morale problem, he left because he had an opportunity to——

Mr. STUPAK. Sure. I am not saying any one of these people left because of morale problems. The report cites the morale problem within the agency. So——

Dr. VON ESCHENBACH. There is clearly from my point of view a need to address the morale and the needs of the people at FDA, and that is a process that is underway. It has come about by, number 1, increasing their numbers and giving them more modern tools to work with, and quite frankly, giving them credit for the incredible job that they are doing as the world's best and finest.

Mr. STUPAK. You held up this Food Protection Plan from November of 2007 in a question from Mr. Barton. This plan doesn't identify any resources to implement it. How much will it cost to implement this plan?

Dr. VON ESCHENBACH. The plan is a strategic plan. It is not a business plan. The business plan to be able to implement that is part of our budget process.

Mr. STUPAK. Are you implementing it?

Dr. VON ESCHENBACH. Yes, sir.

Mr. STUPAK. So you have got to have a budget for implementing it.

Dr. VON ESCHENBACH. Yes, sir.

Mr. STUPAK. What is that budget——

Dr. VON ESCHENBACH. We spent 2008 dollars to implement that.

Mr. STUPAK. OK, 2008 dollars. I am sure that is fiscal year 2008.

Dr. VON ESCHENBACH. Yes, sir.

Mr. STUPAK. How many dollars have you spent in 2008 to implement this plan?

Dr. VON ESCHENBACH. I need to give you that specific number but we have spent 2008 numbers to implement portions of that plan, and I have——

Mr. STUPAK. Well, GAO said that—and again, I asked this question earlier. Without a clear description of resources and strategies, it will be difficult for Congress to assess the likelihood of the plan's success in achieving its intended results.

Dr. VON ESCHENBACH. The success of the plan, Mr. Chairman, is not how much money we are spending on it. That is a critical and important element——

Mr. STUPAK. I agree. It is——

Dr. VON ESCHENBACH [continuing]. To achieve success.

Mr. STUPAK [continuing]. Not how much money.

Dr. VON ESCHENBACH. But success is what the plan actually accomplishes.

Mr. STUPAK. Here is the list. These are recalls last year, 21 pages. We will measure success when I don't come here with 21 pages of recalls. If we don't have the resources, we are to continue with 21 pages of recalls of food, fish, all this——

Dr. VON ESCHENBACH. I agree that we need additional resources and I have requested resources in the budget. I have also held our leadership at FDA accountable in implementation of that report.

Mr. STUPAK. As Members of Congress, we are trying to help you. Mr. Dingell, Mr. Pallone and myself have the Food Safety Bill, which will bring user fees for you. If you put it together at $50 a line, it comes to approximately $900 million in extra money could come to the FDA. Has the FDA—and I have asked you this before and I am sure I going to get the same answer. Have you taken a position on the Dingell-Pallone-Stupak Food Safety Bill, yes or no? Before you said no, and I am sure the answer is still no, right? I can answer that one for you. Since 1996 we have been doing food safety hearings. Since 1996 the FDA has never, never taken a position. How can we help you if you won't even take positions on legislation that number 1, would improve the food safety program which your Science Review Board says is broken. We are trying to give you the resources. You won't even comment on it. How can we work together in a cooperative effort——

Dr. VON ESCHENBACH. Mr. Chairman, there is a request for additional authorities. You would help me a great deal by addressing those additional authorities.

Mr. STUPAK. Well, we would like to help you with that. You won't even tell us how much it costs to implement, where you are getting the resources, what is going to take. I mean, I don't want to be argumentative.

Dr. VON ESCHENBACH. The authorities for us to have mandatory recall would not——

Mr. STUPAK. No, I asked about the Dingell-Pallone-Stupak bill. You won't even take a position on it. It is the most comprehensive bill we have seen in years. It provides you authorities, provides you recall authority, which you don't have now on food, and will actually give you the resources and you won't even take a position on it. So how can we partner to fix the FDA based on Science Review Board's recommendation when the FDA as the Commissioner or your legislative affairs department won't even take a position on simple legislation designed to assist, provide you with the authority and the resources you need?

Dr. VON ESCHENBACH. We continuously are committed and available to provide you any technical expertise you would require——

Mr. STUPAK. Give us the technical expertise on our legislation. Tell us what you like or don't like. You won't even tell us that.

Mr. SHIMKUS. Mr. Chairman.

Mr. STUPAK. Yes, Mr. Shimkus. I am sorry I am over my time.

Mr. SHIMKUS. That Dingell-Pallone-Stupak, would that Stupak be any relation to you?

Mr. STUPAK. That is my brother.

Mr. SHIMKUS. I just want to mention two things, and I highlighted your resume earlier just because you have a long career in public service, working with patients, and again, it is a good thing to highlight. And I want to address your issue of how safe is safe, what is the cost. I mean, both Mr. Stupak and I play sports, we play baseball. You can have a good team, you can have a very successful team, but that team can always get better and that team can get better by bringing in new players, spending—I am not in a big major market area where the Cardinals can't spend what the Yankees spent or the Dodgers spend or the Red Sox spend but it is quality and it is leadership and it is teamwork and it is fitting the pieces of the puzzle together. That is where our questions—I mean, there is a resourcing issue. We understand that.

Dr. VON ESCHENBACH. I couldn't agree with you more, sir, but I have never done an operation in my entire life I didn't ask how can I do it better no matter how well it turned out. I am not before the committee to say that FDA does not have the opportunity to be better and to do more but that is different than saying it is a failure. It is not.

Mr. SHIMKUS. Because I am going to continue to be eating food, you know, tonight and I am going to eat food in the morning and I am going to eat food at lunch and I am assuming it is safe and for 99.99 percent of Americans it is going to be. There is going to be errors. We are going to try to fix that. My colleagues are right to push the envelope and try to get zero defects. We can't get zero defects. I think when you have 21 recalls, I think a broken system would have no recalls. We wouldn't identify any problems and then the problems would emerge. So the fact that there are recalls, the fact is there is a system out there that could be better. We want to help you. I think you identified authorization stuff that we should address. We will have to fight the appropriations battle with our appropriation friends. You have a chance, the fifth time to come back and talk about your budget request, what actually

was put in the budget and how we can help to add more to that. I appreciate your time, and there are votes, Mr. Chairman, I yield back.

Mr. STUPAK. Mr. Walden, you have a question or two?

Mr. WALDEN. Yes, Mr. Chairman, since we are on the third round here.

I want to follow up too on this issue of the recalls because I agree with my ranking member, if there were no recalls we might either be in a perfect world or in a world ready for disaster, because that means people aren't catching problems and it is naturally going to occur, right, in the food chain? You get a contaminant in, some device breaks, something doesn't happen right. I want to minimize those numbers.

Dr. VON ESCHENBACH. Exactly, and——

Mr. WALDEN. Explain how that works.

Dr. VON ESCHENBACH. Well——

Mr. WALDEN. And is that the right metric?

Dr. VON ESCHENBACH. It is an important point because if we are going to continuously respond to the challenges, our systems have to address preventing these problems from ever occurring in the first place, and that is a new area of opportunity in the FDA. It has to strengthen our interventions, which is the inspections, but it also has to have this piece that is the response. When there is a problem, we have to identify it rapidly and intervene before great harm is done. There will be recalls. There will be problems that will develop in these complex systems and, for example, most recently detecting the problem of botulinin contamination. We went in and understood why that botulinin contamination occurred, and not only was that enabling us to fix the problem——

Mr. WALDEN. Was that in the spinach?

Dr. VON ESCHENBACH. That was in canned foods that was being cooked. And not only were we able to identify the problem and get a corrective process there, but disseminate that to other places and have them make modifications in their cooker to prevent the problems from occurring in those places.

Mr. WALDEN. I see.

Dr. VON ESCHENBACH. So response fed right back into prevention. That is what FDA is engaged in and what FDA is doing, and that is in response to Mr. Stupak's concern that we have got to get better, do more and be more effective and that is our commitment and that is the way I think we can go about accomplishing that.

Mr. WALDEN. Dr. von Eschenbach, can you talk to me a little about that food improvement program you are putting forward? Now, I would understand that we are not going to learn about the budgetary costs of that until the President's budget comes out, so you will have some funding requests I assume in the President's budget we will learn about in a week or two that will help underwrite the costs of that. Is that correct?

Dr. VON ESCHENBACH. Right, and in the FDA in the past when it had to regulate spinach, it was regulating spinach in the context of what I grew up with my grandmother, namely that she would take it home and wash it five times and then cook it. Now——

Mr. WALDEN. Until it had lost all its nutritional value too, right?

Dr. VON ESCHENBACH. And FDA has to regulate spinach and lettuce in the context that we stop off at the supermarket, bring home a bag, open it up and turn it upside down. The lettuce comes out already cut along with the croutons and the salad dressing. That is a much different reality. If FDA continued to do things the way it did in the past in the future, we would then fail.

Mr. WALDEN. So this Food Protection Plan——

Dr. VON ESCHENBACH. Is to modernize and to keep pace with the new challenges that are emerging so we continue to be the world's gold standard.

Mr. WALDEN. And so specifically that is a strategic plan. Why don't we have the business plan?

Dr. VON ESCHENBACH. It is going to require resources and authorities. The resources are tracking through the normal budget process. The authorities are the very specific domain of this committee.

Mr. WALDEN. When will you have those requests to us?

Dr. VON ESCHENBACH. Well, the report is published and available for discussion and commentary and implementation. We are looking forward to working with Congress around some of those issues, and many of them have been identified by Congress and, for example, mandatory recalls.

Mr. WALDEN. But the business plan itself, when we will see that?

Dr. VON ESCHENBACH. Well, the business plan will be and is part of the budget process and clearly we have made some initiatives and some direction in that regard in 2008. I look forward to making more and discussing those additional opportunities in 2009 once the President's budget——

Mr. WALDEN. And when did you come out with the strategic plan again?

Dr. VON ESCHENBACH. This plan was introduced just a few months ago.

Mr. WALDEN. So you are going to take it from there to a business plan in what time?

Dr. VON ESCHENBACH. We have already started some of that business plan process and some of the specifics. I will get to the chairman for the record an exact accounting of the dollars that have been applied to this plan as part of our Food Protection Plan. I just don't have it at the table with me.

Mr. WALDEN. And regarding the chairman's legislation on recall and all, have you been invited to testify?

Did we have hearings on that bill yet?

Mr. STUPAK. The full committee has not.

Mr. WALDEN. Has the subcommittee had a hearing on it yet?

Mr. STUPAK. This subcommittee doesn't——

Mr. WALDEN. The Health Subcommittee?

Mr. STUPAK. I don't believe they have.

Mr. WALDEN. You don't think they have had a hearing on your bill?

Mr. STUPAK. No.

Mr. WALDEN. OK.

Mr. STUPAK. But we don't need a hearing to make a decision on legislation.

Mr. WALDEN. Well, we haven't this year, no. Last year, not too many. Anyway, I would be interested to know your opinions too when there is a hearing and you have the invitation to testify on that legislation.

Dr. VON ESCHENBACH. If we are called upon to testify, we certainly would be responsive to that, and asked for technical assistance we would be responsive to that.

Mr. WALDEN. Thank you. Thank you, Mr. Chairman. Thank you, Mr. von Eschenbach.

Mr. STUPAK. Well, that is going to have to conclude and we only have 6 minutes left for a vote, so Dr. von Eschenbach, thank you again for appearing and we look forward to talking to you soon, probably in about 60 days.

Dr. VON ESCHENBACH. Thank you.

Mr. STUPAK. That concludes the questions. I want to thank all of our witnesses for coming today and for the testimony and members for their devotion to this hearing today. I ask for unanimous consent that the hearing record will remain open for 30 days for additional questions for the record. Without objection, the record will remain open.

I ask unanimous consent that contents of our document binder be introduced into the record. Without objection, the documents will be entered in the record.

[The information appears at the conclusion of the hearing:]

Mr. STUPAK. That concludes our hearing, and without objection, this meeting of the subcommittee is adjourned.

[Whereupon, at 2:55 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF HON. JAN SCHAKOWSKI

Thank you, Mr. Chairman - and thank you for your initiative in bringing this important issue before us today. I am eager to hear from our witnesses, many of whom have been immersed in issues surrounding FDA operations for years, and bring particular insight to our hearing today. Thank you for being here.

American's assume that the products they use every day have been tested and approved for safety and effectiveness by some government agency. They may not always know exactly which agency this should be - but they make personal care decisions for themselves and their loved ones based on this assumption. As we'll discuss today, this is not always the case.

This Sunday's Washington Post showed us that toys from China aren't the only products we're using that are laced with dangerous substances. The article, written by Susan D'Amato, highlights the issue of contaminants in cosmetics; lipsticks containing lead, mascaras containing mercury and hair treatments containing formaldehyde.

D'Amato cites a study done by the Campaign for Safe Cosmetics, which tested 33 lipsticks for lead content - several of which exceeded the FDA's lead limit for candy. Why use candy as a benchmark? Because the FDA has yet to set a lead standard for lipstick - in fact, the FDA doesn't even have regulatory authority over cosmetics, nor does it subject cosmetic products or ingredients to premarket approval authority.

On the one hand, we have things that have been approved that shouldn't have been - but on the other - we have potentially life-saving therapies which haven't been approved by FDA - and without a lot of clarity as to why.

Last Spring, amidst cries of foul play, the FDA delayed its approval of Provenge (a therapeutic vaccine for use in terminally ill patients with prostate cancer) against the scientific recommendation of its own advisory committee, which saw the value in bringing patient's the first nontoxic treatment for prostate cancer. This decision has raised concerns of both FDA's ability to review emerging scientific discoveries - and of the need for transparency into the approval process pipeline.

These are two very different, but very alarming illustrations of the challenges which face an outdated, outpaced, and under-resourced FDA. As our witnesses will further detail for us today, the United States is depending on a 1950s FDA facing 21st century demands. This is a stark reality which demands attention and action.

I look forward to working with this Committee and this Congress to overhaul the Food and Drug Administration in a way that will re-establish it as a leader in peer-review, innovation, collaboration and communication.

Again, thank you to the witnesses for being here - and thank your Mr. Chairman. I yield back the balance of my time.

UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE

Garret A. FitzGerald, M.D.
Chair, Department of Pharmacology
Director, Institute for Translational Medicine and Therapeutics
Professor of Medicine and Pharmacology
McNeil Professor in Translational Medicine and Therapeutics

March 11, 2008

The Honorable Jan Schakowsky, Member
Subcommittee on Oversight and Investigations
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

Dear Representative Schakowsky,

Please accept this letter in response to your question which follows:

"Mr. FitzGerald, the Science Board Report states: 'FDA's inability to keep up with scientific advances means that American lives are at risk. While the world of drug discovery and development has undergone revolutionary change – shifting from cellular to molecular and gene-based approaches – FDA's evaluation methods have remained largely unchanged over the last half century.'

I have asked Ms. Cassell to elaborate on the Science Board's findings, and specifically, on how this inadequacy will affect New Drug Applications. Will you please explain more about the scientific implications and how this will affect our ability to get new life-saving therapies to patients in a timely way?"

Drug discovery and development is increasingly configured on what I described as "emerging sciences" in my testimony.

A few examples;

- An understanding that signaling pathways in cells are arranged in dense biological networks that intersect and influence each other to amplify or dampen the transmission of messages is being exploited in drug development. The first new drug based on the detection of an unexpected signaling point in such networks has entered evaluation in humans. This approach is called systems biology. Besides providing insight into "hubs" that might be exploited for beneficial drug action, it is expected also to predict how perturbance of some hubs might result in adverse effects: an early sign of what to look out for. The FDA has no in-house experts in this emerging science.

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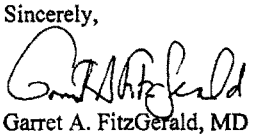
- Increasingly, emphasis is being placed on detailed studies in small numbers of people to try to understand how genetic variation might influence drug response. This requires a lot of expertise in defining the individual characteristics of the patients and how they vary. Again this involves integrating genomic information with novel unbiased assessments of biological response using mass spectrometric measurements of multiple variables. This information is then used to stratify patients to increasingly personalize the advice we can convey based on verification in larger trials. The FDA's in-house strength in genomics and human pharmacology (as distinct from epidemiology) has become seriously depleted and is organizationally fragmented.
- Novel developments in technology are beginning to look at large numbers of proteins and their metabolic products – proteomics and metabolomics – in body fluids at baseline and in response to drugs. It is hoped that these new methodologies will allow us to detect signatures of drug safety and efficacy. The FDA has essentially no in-house expertise in these areas.
- Novel therapies and diagnostics are also based on other emerging sciences – a nice example is RNA, as opposed to DNA. Here we understand that there are multiple ways in which RNA can be regulated and these are being exploited in drug discovery currently and increasingly in drug development. Each of these novel therapeutic approaches – stem cell therapeutics is another good example – have their own particular features. Here again , the ability of the FDA to interact more readily with experts in the academic sector would be likely to enhance the efficiency of consideration and approval of these new potential therapies.

In summary, the agency is configured to respond to a model of drug discovery that will be increasingly subject to radical change. These forces are likely to gather steam as the inefficiency of the current business model – 18 new drugs approved in the past year, perhaps half of them truly innovative – drives innovation.

The agency needs to draw on expertise from outside its ranks to afford it the flexibility to respond to a changing paradigm. It also needs the resources to prompt the best programs in the academic sector to align their efforts with the regulatory science mission of the FDA.

I hope these thoughts are responsive to your request and of help to you and your colleagues as you work to strengthen the FDA.

Sincerely,



Garret A. FitzGerald, MD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 10 2008

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your letter of September 12, 2008, regarding the January 29, 2008, hearing entitled, "Science and Mission at Risk: FDA's Self-Assessment," and the October 11, 2007, hearing entitled "Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply? – Part III." Your letter requested responses to additional questions for the record submitted in two previous letters. We apologize for the delay in providing these responses.

We provided you with responses to the October 11, 2007, Food Safety hearing on September 19, 2008, and we are now providing you with responses to the January 29, 2007, Science Board hearing. As instructed in your letter, we have included FDA's responses to the questions from each Member on the following separate pages.

We have restated each question in bold, followed by our response.

Questions from The Honorable Jan Schakowsky

1. **The Science Board Report states, "Inadequately trained scientists are generally risk-averse, and tend to give no decision, and slow decision or, even worse, the wrong decision on regulatory approval or disapproval."**

    a. **What are you doing in terms of providing leadership that will help fulfill the Food and Drug Administration's (FDA) mandate to speed development, review, and approval of new therapies for patients fighting cancer or other terminal illnesses?**

The Critical Path Initiative, launched in 2004, is FDA's effort to stimulate and assist a national effort to modernize the scientific process—the critical path—through which FDA-regulated products are developed, evaluated, and manufactured. In addition, FDA uses *Fast Track, Accelerated Approval*, and *Priority Review* to make therapeutically important drugs available at an earlier time. These approaches do not compromise the standards for the safety and effectiveness of the drugs that become available through the

process. Finally, user fees have played an important role in expediting the drug approval process since the passage of the Prescription Drug User Fee Act (PDUFA)

Critical Path Initiative

The goal of the Critical Path Initiative, introduced by FDA in 2004, is to facilitate projects and initiatives that will help move the regulatory sciences into the 21st century, enabling us to capitalize on the breakthroughs of basic science. In another area, new bioinformatics approaches are enhancing the interoperability of information tracking systems in the health care environment for all regulated products (e.g., adverse event reporting).

As part of the Critical Path Initiative, FDA is working with the academic community, the public, the pharmaceutical industry, and other Federal health agencies (e.g., the National Institutes of Health (NIH), the Centers for Medicare & Medicaid Services, and the Department of Veterans Affairs) to modernize and transform the development and use of medicines. In 2006, after extensive FDA and public input, we published a list of 76 specific scientific projects with great promise for facilitating development of the path from the laboratory bench to the patient bedside. (The report is available online at http://www.fda.gov/oc/initiatives/criticalpath/.) In addition, we have identified a number of Critical Path Opportunities for Generic Drugs. Examples of projects currently underway include establishing standards for an artificial pancreas, research on drug eluting stents, and biomarker research.

Among many other activities, the Critical Path Initiative also supports the implementation of information technologies that will enable us to tap into existing data repositories to expand research into disease areas, create modeling and simulation tools that leverage prior knowledge, and impact trial design efficiency.

Critical Path efforts will also help lower the costs of medical products to consumers. Just a 10 percent improvement in predicting a drug's failure before clinical trials were started could save $100 million in development costs for that single drug—costs that otherwise may be passed on to consumers through higher insurance premiums or more expensive drugs.

Fast Track, Priority Review, and Accelerated Approval

FDA recognizes that it is important to speed development, review, and approval of new therapies for patients fighting serious or life-threatening illnesses, especially when the drugs are the first available treatment or have advantages over existing treatments. FDA has developed three distinct and successful approaches to making such drugs available as rapidly as possible: *Fast Track, Priority Review, and Accelerated Approval.* These approaches do not compromise the standards for the safety and effectiveness of the drugs that become available through this process.

The table below illustrates the improvement in FDA review times in the years between 1993 and 2003. The median time required to review a priority review drug was reduced from 13.9 months to 6 months.

Comparison of Approval Times for Priority and Standard Review Drugs

Calendar Year	Priority NME & New BLA Approvals		Standard NME & New BLA Approvals	
	Number Approved	Median FDA Review Time (months)	Number Approved	Median FDA Review Time (months)
1993	13	13.9	12	27.2
1994	13	15.0	9	22.2
1995	9	6.0	19	15.9
1996	18	7.7	35	14.6
1997	9	6.4	30	14.4
1998	16	6.2	14	12.3
1999	19	6.3	16	14.0
2000	9	6.0	18	15.4
2001	7	6.0	17	15.7
2002	7	13.8	10	12.5
2003	9	6.7	12	13.8
2004	21	6.0	15	16.0
2005	15	6.0	5	15.8
2006	10	6.0	12	12.5

For your information, we have summarized each approach below.

Fast Track

Fast Track is a **process** designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening conditions that demonstrate the potential to address an unmet medical need. *Fast Track* designation must be requested by the drug company. The request can be initiated at any time during the drug development process. FDA will review the request and make a decision within 60 days. In addition, most drugs that are eligible for *Fast Track* designation are likely to be considered appropriate to receive a *Priority Review*.

Priority Review

Prior to approval, each drug marketed in the United States must go through a detailed FDA review process. In 1992, under PDUFA, FDA agreed to specific goals for improving the drug review time and created a two-tiered system of review times–*Priority Review* and *Standard Review*. A *Priority Review* designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists and the new drug application (NDA) must be reviewed within six months. *Standard Review* provides a ten-month time frame for review and is used for all other NDAs.

Accelerated Approval

In 1992, FDA finalized the *Accelerated Approval* regulation, allowing earlier approval of drugs that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses, and that provide meaningful therapeutic benefit to patients over existing treatments. Under this regulation, FDA can approve certain NDAs on the basis of adequate and well-controlled clinical trials, establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict the product's clinical benefit. Drugs approved under this regulation are made available to patients faster, while the NDA holder continues to study the drug to verify its clinical benefit.

A surrogate endpoint is a marker—a laboratory measurement or physical sign—that is used in clinical trials as an indirect or substitute measurement that represents a clinically meaningful outcome, such as survival or symptom improvement. The use of a surrogate endpoint can considerably shorten the time required to receive FDA approval. FDA bases its decision on whether to accept the proposed surrogate endpoint on the scientific support for that endpoint.

Use of a surrogate can save valuable time in the drug approval process. For example, instead of having to wait to learn if a drug actually can extend the survival of cancer patients, FDA might now approve a drug based on evidence that the drug shrinks tumors because tumor shrinkage is considered *reasonably likely to predict* a real clinical benefit. In this example, an approval based upon tumor shrinkage can occur far sooner than waiting to learn whether patients actually lived longer. The drug company must still conduct studies to confirm that their product extends survival time. These studies are known as Phase 4 confirmatory trials.

If the confirmatory trial does not show that the drug provides a clinical benefit for patients, FDA has regulatory procedures in place that could lead to removing the drug from the market.

PDUFA

The PDUFA program is the cornerstone of modern FDA drug review. PDUFA, enacted in 1992 and renewed in 1997 (PDUFA II), 2002 (PDUFA III), and 2007 (PDUFA IV),

authorizes FDA to collect fees from companies that produce certain human drug and biological products.

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act (FDAAA) of 2007. This law amended the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) and reauthorized some existing provisions of the Act, including the PDUFA provisions (PDUFA IV). The PDUFA IV fee increase supports FDA's activities for drug review, drug safety, drug development, and related priorities authorized by Congress in FDAAA. The PDUFA IV fee increase also allows FDA to improve information technology to support human drug review.

b. How can you improve upon the currently flawed delivery of important new options to patients in a prompt and efficient manner?

FDA clearly appreciates the need to speed development, review, and approval of new breakthrough treatments for patients with serious illnesses. We are constantly striving to find new and innovative ways to facilitate the availability of more effective medicines.

As evidence of this, we have initiated several new approaches to the review and approval of vital treatments for unmet medical needs. These revitalized FDA drug review approaches have yielded tangible results in bringing safe and effective drugs to patients with serious diseases more rapidly. For example, since 1996, 68 drugs for cancer therapies have received priority review and approval. FDA reviewed Gleevec (imatinib mesylate), a treatment for chronic myeloid leukemia, in four months. Shortened review times have also brought promising treatments to patients with HIV/AIDS more quickly. Kaletra (lopinavir/ritonavir) for the treatment of HIV/AIDS, was reviewed and approved in three and a half months. Pegasys (peginterferon alfa-2a), a combination product for the treatment of Hepatitis C, was approved for marketing in four months.

It is important to note that new pharmaceutical therapies, which undergo a more rapid review process, are held to the same rigorous standards of scientific review to ensure their efficacy and safety. Further, it is vitally important that the extra effort and resources devoted to more rapid reviews be targeted carefully, based on scientific merit and medical need.

2. **Unlike food and pharmaceuticals, FDA currently has no pre-market regulatory authority over cosmetic ingredients or products, cannot require pre-market safety testing, cannot mandate that cosmetic-related injuries be reported, cannot require manufacturers to register their cosmetic establishments, and cannot require a product recall unless a court of law finds the product may be injurious for users. Given the emerging science on low-dose effects of and cumulative exposure to chemicals and the Centers for Disease Control and Prevention's documentation of the accumulation of the chemicals found in personal care products in the body fluids of children and**

adults, is FDA conducting any safety reviews looking at the cumulative and low-dose effects of these chemical exposures?

The Centers for Disease Control and Prevention's (CDC) National Report on Human Exposure to Environmental Chemicals provides an analysis of environmental chemicals and their metabolites that are excreted in the urine of study participants. The report specifically states that its findings do not establish an association between exposure to these chemicals and adverse effects on human health. Some of the environmental chemicals and their metabolites that are referenced in CDC's report may be found in cosmetics, over-the-counter (OTC) drugs, or other personal care products. Many of them also come from other sources in the human environment that are not subject to FDA regulatory authority.

Under section 601(a) of the FD&C Act, 21 U.S.C. 361, a cosmetic is adulterated if "it bears or contains any poisonous or deleterious substance which may render it injurious to users *under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual...*" (emphasis added). FDA's review of ingredient safety may address, where appropriate, effects from exposure to small quantities of a chemical, in addition to cumulative exposure.

FDA has other requirements (21 CFR Part 700, Subpart B) for specific ingredients that may be used in cosmetic preparations. In addition, FDA has studied the effects of long-term use of alpha hydroxy acids (AHAs), resulting in the issuance of guidance for industry on the labeling of products that contain these ingredients, in order to ensure their safe use (available on our Web site at http://www.cfsan.fda.gov/~dms/ahaguid2.html).

More recently, FDA has been evaluating the safety of phthalate esters used in cosmetic products. Our scientists developed an analytical method to determine the levels of phthalate esters in cosmetics and the results of our survey of products for phthalate levels was recently published ("Analysis of Consumer Cosmetic Products for Phthalate Esters," J.C. Hubinger and D.C. Havery, *Journal of the Society of Cosmetic Chemists*, (2006) vol. 57, pp. 127-137). We are currently beginning a more extensive survey to obtain information for determining human exposure to phthalates from the use of cosmetic products.

3. **Is FDA conducting any studies on the use and timing of chemical exposures from personal care products and cosmetics, specifically for young children?**

As noted in response to Question 2, not all "personal care products" are regulated as cosmetics under the law. Those products regulated as drugs are subject to the requirements for drugs, including premarket evaluation of their safety and effectiveness before they are approved for introduction into the marketplace or adherence to restrictions specified in the OTC drug monographs.

Also as noted in the response to Question 2, FDA is beginning a survey of cosmetics products to determine the levels of phthalates in current use. The survey includes cosmetic products marketed for use by infants and children, because, like all consumers, they are exposed daily to phthalates from a number of sources, including air, drugs, food, plastics, water, and cosmetics. FDA's laboratory survey will help us to more accurately assess their exposure to phthalates from cosmetics specifically. FDA is also conducting a study to determine levels of the contaminants 1,4-dioxane and ethylene oxide in children's cosmetic products.

4. **Is FDA—or any other Federal agency to your knowledge—conducting any studies on worker exposures to unsafe chemicals used in the cosmetics industry?**

Worker safety is primarily under the purview of the Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health. These agencies have conducted or sponsored studies of workplace exposure to chemicals that are used as cosmetic ingredients and also used in other products and settings. In addition, EPA has published information relevant to worker safety, such as safety resources for nail salons, available at www.epa.gov. Professional practice, such as in salons, is generally regulated by state and local authorities.

FDA keeps abreast of relevant studies conducted by its sister agencies and other scientific bodies, including studies related to worker safety, which may yield information useful in assessing the safety of direct use of cosmetics by consumers.

5. **How many staff does FDA's Office of Cosmetics and Colors have and what is its annual budget?**

In FY 2008, FDA received additional appropriated funds specifically for the cosmetics program. The Center for Food Safety and Applied Nutrition (CFSAN) estimates that tis appropriated FY 2008 budget for the Office of Cosmetics and Colors (OCAC) will support 16 full-time equivalent (FTE) positions and provide $2.7M for the cosmetics activities conducted by OCAC. The Color Certification Program is supported by user fees and is not provided for by any appropriated funds.

6. **A recent editorial in the journal of Nature Biotechnology [Vol.26. Number 1, January 2008], a peer-reviewed scientific journal, calls for an explanation by the Food and Drug Administration (FDA) of why it ignored the advisory committee's positive recommendation for the cancer vaccine Provenge. It argues that, at the very least, FDA should explain its decision for the good of those developing other cancer vaccines, who would welcome this clarity in order to better develop their products. Do you have any thoughts on how this decision affected the ongoing research of other cancer treatment developers?**

FDA is aware of the editorial in the journal of Nature Biotechnology [Vol.26. Number 1, January 2008]. At FDA, providing the American public with safe and effective medical products is our core mission. We base important decisions, such as to allow specific human studies of an investigational product, or to approve a product on the available scientific information and a careful evaluation of risks and benefits to patients.

While FDA takes very seriously, and carefully considers, the advice of its advisory committees, the committees' recommendations are advisory in nature and the Agency is not bound by these recommendations. FDA makes a decision on whether a product should be approved after evaluating all data and considering the recommendations of the advisory committee.

FDA's Center for Biologics Evaluation and Research (CBER) helps facilitate the development, approval, and access to safe and effective biological products. CBER often provides guidance to sponsors during the application review process, and we will continue to provide guidance when requested by a sponsor. Under applicable laws and regulations, including 21 CFR 601.50 and 21 CFR 601.51 (d)(1), information provided to FDA concerning a specific product is not available for public disclosure prior to licensure of the product.

The Honorable Jay Inslee

1. **Since the hearing, have you explored FDA's Extradition options and whether it has such authority in these cases?**

FDA consults with the Department of Justice (DOJ) in matters of extradition. Each decision must be made on a case-by-case basis. After sufficient review, DOJ makes the decision whether or not to pursue extradition. FDA does not comment on pending matters.

2. **What are the legal parameters within which the FDA has to act regarding extradition?**

U.S. law defines the legal parameters for extradition to the United States. As previously stated, DOJ, not FDA, makes extradition decisions based on the law and DOJ policy. FDA does not have specific authority to effect extradition.

3. **If the authority exists, what action has FDA taken toward extradition in these cases?**

The authority for extradition resides with DOJ. FDA consults with DOJ on a case-by-case basis regarding matters of extradition to the United States. FDA does not comment on open or pending matters.

4. **If you have not considered extradition, why not?**

As previously stated, DOJ decides matters of extradition. FDA consults with DOJ on a case-by-case basis regarding matters of extradition to the United States. FDA does not comment on open or pending matters.

5. **What efforts has FDA made towards extraditing individuals who import devices that are illegally marked [sic] in the United States?**

FDA consults with DOJ in matters of extradition. DOJ makes the decision whether or not to pursue extradition action.

The Honorable Marsha Blackburn

1. **Today we have heard testimony from several witnesses on the massive burdens placed on FDA with regards to regulating the U.S. food supply, pharmaceuticals, etc. I am concerned with problems your agency is facing in meeting your current regulatory obligations, yet others want to pile on another monumental task by requiring FDA to regulate tobacco as well. Regulating tobacco would not only divert attention away from the agency's traditional functions, but would also force the agency into uncharted waters, such as investigating and preventing cigarette smuggling.**

   A. Can FDA handle the additional task of regulating tobacco?

   The program created by H.R. 1108, to regulate tobacco products, would be comprehensive and would require the Agency to create a new Center to implement the program. If the bill becomes law, it is essential that FDA be provided adequate resources to carry out those new authorities.

   B. Do you have concerns that regulating tobacco will further compromise FDA's ability to protect the Nation's food and drug supplies, two of FDA's most important roles?

   In order to avoid compromising FDA's ability to carry out its mission, it is essential that the Agency be provided with adequate resources to implement any new responsibilities it is given.

2. **You stated in an interview with *The Hill* newspaper on January 24 that you need to present a game plan for how increased funds will be used, and what the return on investment would be for the American people.**

   A. Can you tell us what the return on investment might be if FDA was compelled to regulate tobacco?

   In *The Hill* interview, the Commissioner was addressing a means for how FDA would use additional funds, if provided. In the case of regulating tobacco, Congress would be asking the Agency to take on additional responsibility. We agree that it would be important to understand the return on investment for this program. The extent to which there will be a return on investment will depend on whether FDA is adequately funded to carry out a tobacco program.

   B. Also, in that same interview, you said that you wanted FDA to be a bridge and not a barrier to getting new solutions to patients. Could FDA be a bridge for tobacco products under the current legislative proposals moving through Congress?

If H.R. 1108 is enacted, FDA would seek to implement the tobacco legislation in a manner consistent with its express provisions. Our understanding is that the legislation would allow marketing of tobacco products that meet the standards of the legislation.

Please let us know if there are further questions.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

May 21, 2008

The Honorable John D. Dingell, Chairman
Committee on Energy and Commerce

Dear Representative Dingell and Stupak:

On behalf of the former members of the Subcommittee on Science and Technology of the FDA Science Advisory Board, I again thank you for your interest in our report: "FDA Science and Mission at Risk." Our conclusions were serious and troubling, so we are grateful that Members of Congress see the need to address the concerns we raised.

Pursuant to your request of February 29, 2008, I have attached my response to the additional questions posed by Members Shimkus and Schakowsky following the hearing held by the Subcommittee on Oversight and Investigations held January 29.

I appreciate your sensitivity to the fact that the Subcommittee completed its work and was thus disbanded by the FDA Science Board on December 3, 2007. As Chair of the Subcommittee that prepared the report and the witness that summarized the overall findings of our report in the hearing on January 29, I personally have prepared the attached responses. However, on behalf of this group, I emphasize that we remain available to each of you in our common pursuit of a stronger FDA that has the resources it needs.

Sincerely,

Gail H. Cassell

Gail H. Cassell, Ph.D., D.Sc.(hon)
Vice President, Scientific Affairs and
Distinguished Lilly Research Scholar for Infectious Diseases
Eli Lilly and Company

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce
The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations
The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations
The Honorable Jan Schlkowsky, Member
Subcommittee on Oversight and Investigations

RESPONSE TO QUESTIONS POSED BY THE HONORABLE JOHN SHIMKUS
Submitted by Gail H. Cassell, Ph.D. in the capacity of Chair of the FDA Science Board Subcommittee on Science and Technology

Question 1

To clarify for the record, the budget estimating performed by the Subcommittee: Tab 10 of the hearing document binder, entered into the record, contains a document entitled: "Budget Justification," which outlines upwards of $1.2 billion in additional FDA funding.

a. Was this the estimated budget prepared by the Subcommittee on Science and Technology as it drafted its report for the Science Board? If so, what were the Sources and how did the Subcommittee assess and prepare these estimates.

b. Did the Science Board consider or accept this information in its deliberations over the Subcommittee Report?

c. How does this information differ from budget estimates noted in the report, and is this information essential for understanding the findings and recommendations committee's report to the board?

Response 1

The budget estimate under Tab 10 was prepared by the Subcommittee during the course of its work. The Subcommittee was composed of three members of the Science Board and 30 other experts representing industry, academia and other government agencies. As described in the report, the Subcommittee was divided into working groups each of which reviewed a different center within the agency and three cross-cutting areas. The working groups included: CDER, CBER, CDRH, NCTR, CFSAN/CVM, Genomics, Information Technology, and Biostatistics and Surveillance.

While the Subcommittee was asked to review gaps in science and technology and not to assess available resources, it rapidly became apparent that the gaps were so intertwined with two decades of inadequate funding that it was impossible to assess one without the other. The Subcommittee found that FDA's resource shortfalls have resulted in a plethora of inadequacies that threaten our society—including, but not limited to, inadequate inspections of manufacturers, a dearth of scientists who understand emerging new science and technologies, inability to speed the development of new therapies, an import system that is badly broken, a food supply that grows riskier each year, and an information infrastructure that was identified as a source of risk in every FDA Center and function. The Subcommittee concluded that FDA can no longer fulfill its mission without substantial and sustained additional appropriations. Thus each of the Subcommittee working groups felt it was critical to develop realistic budget estimates for implementation of their recommendations to address the gaps. In addition, Peter Barton Hutt, a member of the Subcommittee and former Chief Counsel of the FDA, was

requested by the Chair of the Subcommittee to review the recent budget history of the FDA in the context of its roles and responsibilities.

The Subcommittee was in a unique position to develop reliable estimates of the resources required to implement the recommendations of its report. The Subcommittee membership had extensive experience in development and management of large R & D budgets and regulatory groups, including budget development and oversight for entire pharmaceutical companies (i.e. former CEO Merck; heads of research and development of Genentech, Abbott, Monsanto) and universities (Dean, Iowa State School of Agriculture; Dean, University of Texas Southwestern School of Medicine). The Subcommittee membership also included an economist with expertise in workforce issues, a former Assistant Secretary of Health and Human Services, and as already mentioned, a former Chief Counsel of the FDA. In addition, despite the lack of access to internal data, the Subcommittee was able to review publicly available information and directly observe the overall stress within the Agency while conducting this review. Finally, as the Subcommittee became cognizant of the seriousness of the FDA's deficiencies and the magnitude of the crisis, the Subcommittee spent considerable effort garnering as much information as possible about the current roles and responsibilities of Agency staff and currently available resources.

The Subcommittee also had exceptional expertise in budget development and oversight with respect to developing budgets for emerging sciences, food safety and information technology. Members included leaders of relevant research institutes (founders and leaders of the Institute for Translational Medicine and Therapeutics at the University of Pennsylvania, the Institute for Systems Biology, the Broad Institute Harvard/MIT, Brown Institute of Molecular Medicine in the University of Texas Health Science Center Houston), research intensive departments in academic institutions (departmental chairs from University Pennsylvania., University of Alabama Birmingham, University of Wisconsin), and other government agencies (i.e. HHS, NIH, CDC, USDA), a former Under Secretary for Food Safety, a VP of Information Technology of two major pharmaceutical companies, the Assistant Chief Information Officer for the Center for Infectious Diseases of the CDC and leader of the IT Influenza Pandemic Preparedness team of CDC.

Based upon their best professional judgment and publicly available information, the Subcommittee budget estimates were summarized and linked to the major recommendations. Of course, the Subcommittee realizes these estimates have several associated caveats. One is that the FDA, as part of the administration, is required to support the resource needs identified in the President's budget. As a result, the Subcommittee was unable to incorporate internal FDA estimates of what is needed to address the deficiencies noted. Another is a lack of data. The Agency does not have a historical budget database, and as a result the Subcommittee was not in a position to conduct a zero-based budget analysis for FDA.

In addition to its own estimates, the Subcommittee also drew heavily from estimates of other knowledgeable groups that had developed detailed budget estimates for food safety

(Alliance for a Stronger FDA whose Board membership includes three former FDA Commissioners and two Secretaries of HHS plus former FDA officials) and drug safety (the Institute of Medicine of the National Academies of Science). In the Budget Justification under Tab 10, these outside sources are directly linked to the recommended amounts. The outside sources are also referenced in detail in the body of the original report. The sources used by Mr. Hutt for his recommendations are given in detail in Appendix B of the original report.

Draft versions of the report did contain a table with an itemized breakdown similar to that in Tab 10. The table was used in multiple discussions by the Subcommittee and served as the basis for the statements about resource needs in the final report. However, the budget justification provided under Tab 10 was not presented in that form to the Science Board nor was it included in the body of the final written report or the appendices. The budget information and recommendations of Mr. Hutt were all included in Appendix B of the final written report, were presented by Mr. Hutt to the Science Board, and submitted for the written record of the Oversight Committee's hearing during Mr. Hutt's testimony before the Committee on Januarary 29.

On December 3, 2007 the Subcommittee officially transmitted their report, FDA Science and Mission at Risk, to the full Science Board. The Board unanimously accepted the report, including the overall budget recommendations.

Question 2

The Budget Justification document contains $160 million in estimated funds for the Office of Regulatory Affairs (ORA), which serves the inspection function for the agency.

a. Does the Subcommittee estimate in its report how many new inspectors would be necessary—in ORA's current set up—to evaluate imports and conduct domestic and foreign inspections of food facilities, and drug and device manufacturing facilities? If so, how many? And how many inspectors would be necessary should FDA implement its recently completed ORA revitalization plan?

b. Did the Subcommittee evaluate whether the ORA presently is capable of managing effectively the demands of burgeoning imports and foreign drug manufacture should it receive more resources?

Response 2

The Subcommittee did not perform an in depth review of ORA. The committee did not feel it had the adequate expertise, nor time necessary, to do justice to this complex but critical area of FDA's responsibilities. The Subcommittee did recommend that the Science Board undertake a thorough review of ORA paying particular attention to the gaps in science and technology identified that would have an impact upon ORA. Therefore, the Subcommittee cannot provide absolute answers to Question 2. However, based upon data presented to the Subcommittee by the FDA in terms of the number of sites outside the United States to be inspected (>300,000 in over 100 countries) and given the decrease in appropriated funds detailed in Appendix B of the report, one can conclude that ORA is not currently capable of providing the proper oversight.

Question 3

Appendix B to the Subcommittee report contains the following language: "The report was prepared as part of Mr. Hutt's service on the Science Review Subcommittee...and reflects his personal analysis and opinion on matters considered by the Subcommittee." Did the Subcommittee adopt or accept this appendix as fully representing the Subcommittee's views on the budget and resource needs of the agency?

Response 3

The Subcommittee unanimously agreed with the findings and need to essentially double the appropriated funds and personnel. However, some committee members felt that the agency could not responsibly absorb a doubling within the first year as was recommended by Mr. Hutt but rather that there should be a phased-in approach based upon a science business plan to be developed within an upgraded science organization led by a new chief scientific officer and new scientific directors in each of the centers (as recommended in the Subcommittee's report).

Question 4

The Subcommittee report recommends that its plan "be aligned with the 2009 budget process in order to align the resources with the proposed response." Clearly, the President's current budget proposal was nearly completed by the time this report was released. Did you expect the FY2009 budget proposal presented by President Bush in February to contain substantial alignment with your recommendations? If not, what did the Subcommittee mean by this recommendation? Please elaborate.

Response 4

The Subcommittee did not expect the President's budget would align with our recommendations. However, the Subcommittee was hopeful that because of the

seriousness of the deficiencies noted and the urgency with which they need to be addressed, that the resource recommendations would be taken into account by the Congress in their appropriations of funds for the FDA during the FY09 budget process.

Question 5

Will you work with this Committee, on a bi-partisan basis, to help develop strong, bi-partisan agreement on resource recommendations?

Response 5

All members of the Science and Technology Subcommittee remain committed to working with each member of Congress in the common pursuit of a stronger FDA that has the resource it needs. For example, following the hearing of the Subcommittee on Oversight and Investigations at the request of Congressmen Dingell, Waxman, Stupak and Pallone, the budget estimates in Tab 10 were used by some former members of the Science and Technology Subcommittee to develop a more detailed breakdown of the resources required to implement the recommendations of the report. Even though the Science and Technology Subcommittee had been disbanded upon acceptance of its report, all but four members (two who were unavailable and two who were government employees) reviewed and gave their signature in support of the more detailed analysis.

RESPONSE TO QUESTION FROM THE HONORABLE JAN SCHAKOWSKY
Submitted by Gail H. Cassell, Ph.D. in the capacity of Chair of the FDA Science Board Subcommittee on Science and Technology

Question

Ms. Cassell, the Science Board Report states: "FDA's inability to keep up with scientific advances means that American lives are at risk. While the world of drug discovery and development has undergone revolutionary change shifting from cellular to molecular and gene-based approaches—FDA's evaluation methods have remained largely unchanged over the last half century."

Could you please expand on this a bit more—my concern is that for example, New Drug Applications for cancer are being evaluated based on standards of traditional chemotherapeutic approaches. What does this mean for our ability to bring new, life-saving drugs to patients?

Response

The central challenge for the FDA is to protect consumers while supporting the efficient development of new products to promote health. In order to respond to this challenge, FDA-relevant biology and medicine in the 21st century must make use of the growing knowledge about the enormous complexity of living organisms. The FDA must be ready and able to embrace new approaches to understanding and applying biology. It is vital to the public health that FDA be prepared to lead the way; not only by effectively anticipating and responding to the paradigm changes described in the Subcommittee's report, but by anticipating and responding to the as yet unidentified advances in medicine.

The FDA must have the scientific and information base to understand changes in medicine to advance the treatment of important diseases. The scientific paradigm of the past 30 years, which was based on the targeting of specific enzymes, receptors and ion channels and advances in understanding nutrition, has enabled the discovery and development of important medicines and vaccines that have had enormous impacts on both human and animal health. Yet effective treatments for a wide variety of diseases, such as many forms of cancer, Alzheimer's Disease, Parkinson's Disease, etc., have been difficult to find because of the complexity of the molecular bases of these diseases. The success of the human genome project in deciphering the genetic code of biological information has changed the level of scientific understanding in two important ways. First, a complete parts list of all human genes is becoming increasingly complete, so that the component parts of the complex system can be delineated. Second, a view of biology as an information science has emerged. It is clear that biological information is acquired, transmitted, integrated and distributed by biological networks, to the molecular machines. These two insights have generated a whole new strategy: a 'systems approach' to understanding health and disease. This systems view has significant implications for the products used in diagnosis, therapy and even prevention. It provides

completely new and powerful strategies for approaching these tools of contemporary medicine, because we are now moving from having the complete parts list to learning how these parts function together in networks and systems. The challenge that the FDA faces is that systems approaches require a cross-disciplinary environment in which biology, medicine, technology and computation/mathematics can be seamlessly integrated.

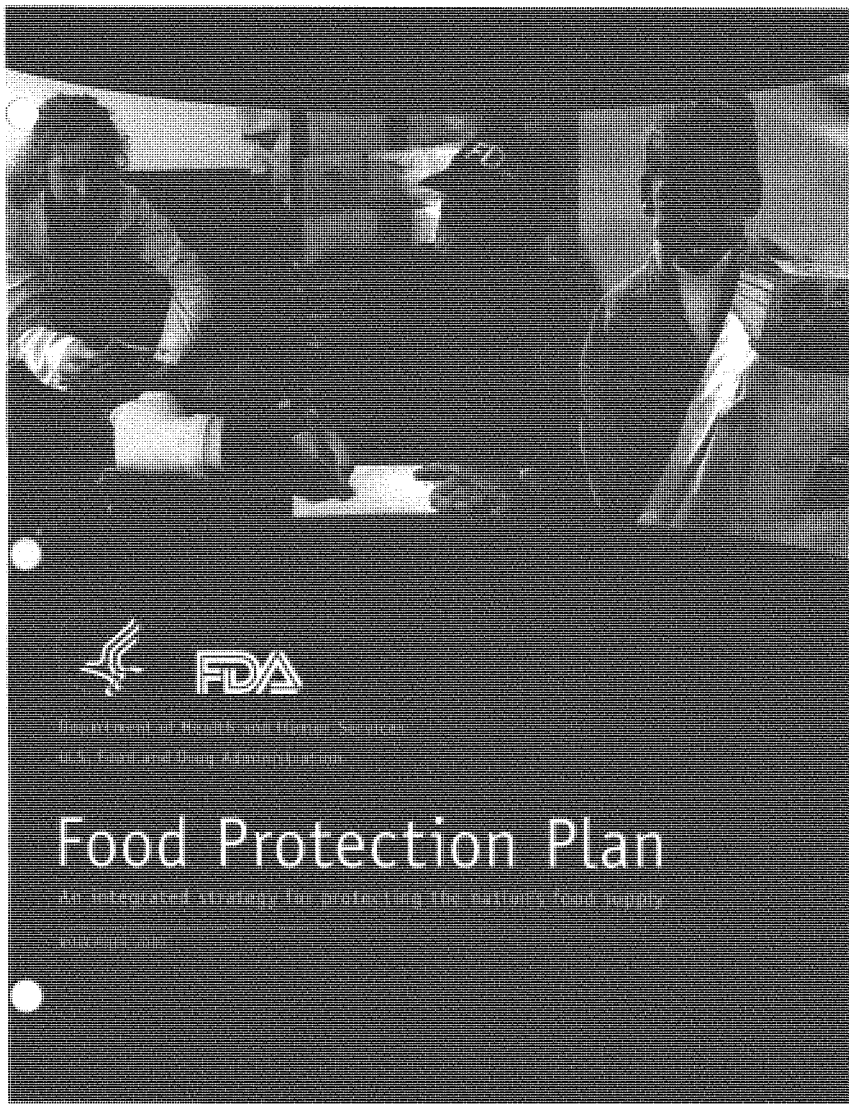
In addition to the emergence of a systems approach to medicine, the FDA must take advantage of two other forces that are revolutionizing medicine (and biology). These are: the development of powerful new measurement (nanotechnology) and in vivo imaging technologies; and, the pioneering of new mathematical and computational tools for acquiring, storing, validating, mining, integrating, visualizing and modeling biological information.

The resulting paradigm shift is that medicine will move from its current, largely reactive, mode to one that is predictive, personalized, preventive and participatory. This new medicine will lead to a digitalization of medicine (e.g. the analysis of biological information from single molecules, single cells and even single individuals). This, in turn, will have an even larger impact on medicine than did the digitalization of information technologies and communications. This will require similarly significant advances in the information technology arena to support novel data and information needs that are arising from rapidly evolving new sciences and their exciting applications.

These same systems changes will come to all areas of biology relevant to the FDA—agriculture, food, nutrition, toxic environmental responses, etc. Furthermore, there are many other emerging sciences that are rapidly evolving and contributing to the complexity of this new paradigm such as, wireless technology, robotics, regenerative medicine, combination products, medical imaging, etc. While there is debate about how rapidly the new paradigm will become reality, no one questions the urgent need for the FDA to put mechanisms in place to be able to monitor and access knowledge and expertise in these emerging sciences.

EXHIBIT BINDER INDEX

1. U.S. Food and Drug Administration (FDA) report, ″Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply,″ November 2007
2. Report to the President by the Interagency Working Group on Import Safety, subject: ″Action Plan for Import Safety: A Roadmap for Continual Improvement,″ November 2007
3. National Antimicrobial Resistance Monitoring System (NARMS) Program Review, conducted by the External Subcommittee of the FDA Science Advisory Board, 5/25/07
4. Federal Register, volume 73, no. 3, subject: ″Department of Health and Human Services, FDA: Request for Comments on the Science and Technology Report; Establishment of Docket; Request for Comments,″ 1/8/08
5. Charter, Science Board to the Food and Drug Administration, 6/26/06
6. Congressional Research Service Report to Congress by Judith Johnson, et al.; subject: ″The Food and Drug Administration: Budget and Statutory History, FY1980–FY2007,″ 1/24/2008
7. Letter from Kenneth Shrine, from The University of Texas System, to FDA Commissioner Andrew von Eschenbach, 01/22/08
8. Letter from Kenneth Shrine to Dr. Gail Cassell, member of the FDA's Science Board, 01/23/08
9. New York Times article by Gardiner Harris, re: ″Advisers Say F.D.A.'s Flaws Put Lives at Risk,″ 12/1/07
10. FDA's Science Board Budget Justification

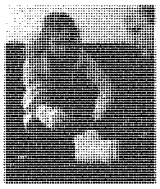

FDA
Food Protection Plan

"Americans enjoy unprecedented choice and convenience in filling the cupboard today, but we also face new challenges to ensuring that our food is safe. This Food Protection Plan will implement a strategy of prevention, intervention and response to build safety into every step of the food supply chain."

Michael O. Leavitt

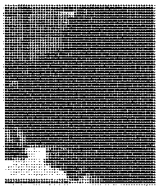
Secretary of Health and Human Services
U.S. Department of Health and Human Services

Cover Photos



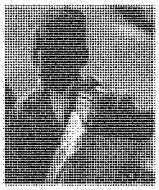
An investigator from the FDA's San Francisco District (left) working with an investigator from the California Department of Health Services, collecting soil samples as part of an investigation into an *E. coli* outbreak in spinach.

Black Star/Steve Yeater for FDA



A senior import specialist in FDA's New York District, reconciling importers' invoices with shipping labels and collecting samples at a food warehouse.

Black Star/Michael Falco for FDA



Today's consumers have come to expect increased levels of convenience and choice, both of which contribute to the need for a global food supply.

Getty Images

A MESSAGE FROM THE COMMISSIONER

As a physician and the Commissioner of Food and Drugs, protecting America's food supply is extremely important to me.

American consumers have one of the safest food supplies in the world, but the world is changing and we know it can be safer. New food sources, advances in production and distribution methods, and the growing volume of imports due to consumer demand call for a new approach to protecting our food from unintentional or deliberate contamination. The U.S. Food and Drug Administration (FDA) must keep pace with these changes so that the safety of the nation's food supply remains second to none.

In the past few years, FDA has introduced several initiatives that address microbial and other food safety hazards with domestic or imported produce and that guide industry practices in the safe production of fresh-cut fruits and vegetables. FDA has also worked hard to raise awareness about food defense issues and preparedness. These are just a few things we are doing to improve food safety and food defense.

Recent nationwide recalls remind us how devastating foodborne illness can be. In the past year, contaminated peanut butter led to illnesses in more than 300 people and at least 50 hospitalizations. Contaminated spinach resulted in 206 illnesses, three deaths, and more than 100 people hospitalized. Reports of kidney failure and deaths in cats and dogs prompted a recall of more than 100 brands of pet food.

For every one of these emergencies, the FDA responded immediately to minimize harm. FDA investigators traced each problem's source and worked without delay to remove the affected products from market shelves. FDA staff continue to work diligently to protect our food supply, by containing outbreaks and preventing further illnesses.

With this FDA Food Protection Plan we are going even further. It is a forward-oriented concept that uses science and modern information technology to identify potential hazards ahead of time. By *preventing* most harm before it can occur, enhancing our intervention methods at key points in the food production system, and strengthening our ability to respond immediately when problems are identified, FDA can provide a food protection framework that keeps the American food supply safe.

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

TABLE OF CONTENTS

FDA is implementing a Food Protection Plan (the Plan) that addresses both food safety and food defense for domestic and imported products. The Plan is integrated with the Administration's Import Safety Action Plan. The Food Protection Plan operates through a set of integrated strategies that:

- Focus on risks over a product's life cycle from production to consumption
- Target resources to achieve maximum risk reduction
- Address both unintentional and deliberate contamination
- Use science and modern technology systems

FDA's Integrated Strategy Provides Three Elements of Protection

PREVENT Foodborne Contamination

- Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses
- Identify Food Vulnerabilities and Assess Risks
- Expand the Understanding and Use of Effective Mitigation Measures

INTERVENE at Critical Points in the Food Supply Chain

- Focus Inspections and Sampling Based on Risk
- Enhance Risk-Based Surveillance
- Improve the Detection of Food System "Signals" that Indicate Contamination

RESPOND Rapidly to Minimize Harm

- Improve Immediate Response
- Improve Risk Communications to the Public, Industry and Other Stakeholders

FDA recognizes the need to partner with Congress to make the changes necessary to transform the safety of the nation's food supply. This Plan identifies the administrative actions we are proposing to take within the Agency. This Plan also recommends legislative changes to strengthen FDA's ability to continue to protect Americans from foodborne illnesses.

Additional Protections that Involve Legislative Changes to FDA's Authority

PREVENT Foodborne Contamination

- Allow FDA to Require Preventive Controls to Prevent Intentional Adulteration by Terrorists or Criminals at Points of High Vulnerability in the Food Chain
- Authorize FDA to Issue Additional Preventive Controls for High-Risk Foods
- Require Food Facilities to Renew Their FDA Registrations Every Two Years, and Allow FDA to Modify the Registration Categories

box continued on page 4 ...

box continued from page 3 ...

INTERVENE at Critical Points in the Food Supply Chain

- Authorize FDA to Accredit Highly Qualified Third Parties for Voluntary Food Inspections
- Require New Reinspection Fee From Facilities That Fail to Meet current Good Manufacturing Practices (cGMPs)
- Authorize FDA to Require Electronic Import Certificates for Shipments of Designated High-Risk Products
- Require New Food and Animal Feed Export Certification Fee to Improve the Ability of U.S. Firms to Export Their Products
- Provide Parity Between Domestic and Imported Foods if FDA Inspection Access is Delayed, Limited, or Denied

RESPOND Rapidly to Minimize Harm

- Empower FDA to Issue a Mandatory Recall of Food Products When Voluntary Recalls Are Not Effective
- Give FDA Enhanced Access to Food Records During Emergencies

FDA plans to enhance its information technology (IT) capabilities to fully support the implementation of the FDA Food Protection Plan.

For More Information

For follow up information on this report, contact:

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Email: FoodProtection@fda.hhs.gov

To download a copy of this report, go to *http://www.fda.gov/oc/initiatives/advance/food/plan.html* or for the PDF version go to *http://www.fda.gov/oc/initiatives/advance/food/plan.pdf*

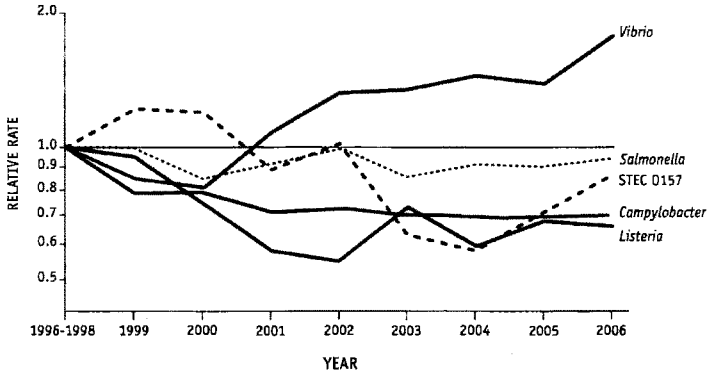
For more in-depth information on the many programs FDA has underway to protect the nation's food supply, go to the Food Protection main page at *http://www.fda.gov/oc/initiatives/advance/food.html*

II. INTRODUCTION

Every day across the country, people eat out, buy groceries, and cook meals for their families. Americans expect that all their food will be safe, and FDA plays a critical role in making sure this is true. FDA is responsible for the safety of the vast range of food Americans eat; about 80 percent of all food sold in the United States. This includes everything except for meat, poultry, and processed egg products, which are regulated by the U.S. Department of Agriculture (USDA).

In May 2007, Secretary of Health and Human Services Michael O. Leavitt and Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D., charged FDA with developing a compre-

Relative rates compared with 1996-1998 baseline period of laboratory-diagnosed cases of infection with *Campylobacter*, STEC O157, *Listeria*, *Salmonella* and *Vibrio*, by year.



Under its FoodNet program (*www.cdc.gov/foodnet*), the Centers for Disease Control and Prevention (CDC) monitors foodborne microorganisms that cause illness and tracks trends. This graph shows the progress that has been made in reducing foodborne infections. Other than recent increases in *Vibrio*- and Shiga toxin-producing *Escherichia coli* (STEC) O157-related illness, the incidence of illnesses associated with these foodborne microorganisms has mostly remained steady or gone down since the late 1990s, although further progress is needed. Note that the graph represents all illnesses associated with the five types of bacteria, not just that from contaminated food. The graph also represents illnesses from foods not regulated by FDA.

Source: Centers for Disease Control and Prevention

hensive and integrated FDA Food Protection Plan to keep the nation's food supply safe from both unintentional and deliberate contamination. Driven by science and modern information technology, the Plan aims to identify potential hazards and counter them before they can do harm. A cornerstone of this forward-thinking effort is an increased focus on prevention.

The Plan builds in safety measures to address risks throughout a product's life cycle, from the time a food is produced to the time it is distributed and consumed. The Plan focuses FDA's efforts on preventing problems first, and then uses risk-based interventions to ensure preventive approaches are effective. The Plan also calls for a rapid response as soon as contaminated food or feed is detected or when there is harm to people or animals.

FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: prevention, intervention and response.

FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: prevention, intervention and response.

- The *prevention* element means promoting increased corporate responsibility so that food problems do not occur in the first place. By comprehensively reviewing food supply vulnerabilities and developing and implementing risk reduction measures with industry and other stakeholders, FDA can best address critical weaknesses.
- The *intervention* element focuses on risk-based inspections, sampling, and surveillance at high risk points in the food supply chain. These interventions must verify that the preventive measures are in fact being implemented, and done so correctly.
- The *response* element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency. It also includes the idea of better communication with other federal,

state, and local government agencies and industry during and after emergencies. Whether contamination is unintentional or deliberate, there is a need to respond quickly and to communicate clearly with consumers and other stakeholders. The communication should emphasize identifying products of concern as well as assuring the public of what is safe to consume.

FDA is committed to strengthening the nation's food protection system through implementation of the FDA Food Protection Plan. The Plan's strategic and partnered activities are driven by science and incorporate the use of 21st-century technologies.

Scope of the Food Protection Plan

1. Applies to food for people and animals
2. Addresses domestic and imported products
3. Encompasses food safety (unintentional contamination) and food defense (deliberate contamination)

FDA Regulates Roughly 80 Percent of the U.S. Food Supply

- FDA regulates $417 billion worth of domestic food and $49 billion in imported food[1] annually.
- FDA has oversight of more than 136,000 registered domestic food facilities (including more than 44,000 U.S. food manufacturers and processors and approximately 113,000 U.S. food warehouses, including storage tanks and grain elevators).[2]
- FDA or state and local authorities regulate more than 2 million farms, roughly 935,000 restaurants and institutional food service establishments, and 114,000 supermarkets, grocery stores, and other food outlets.[3] FDA provides guidance, model codes, and other technical assistance to state and local partners.
- Approximately 189,000 registered foreign facilities manufacture, process, pack, or hold food consumed by Americans.

1 Based on FDA value-of-shipment information, 2003.

2 Facilities that are engaged in more than one type of activity (e.g., manufacturing and warehousing) are counted in both categories; thus, the sum of the individual numbers of type of facilities exceeds the number of total registered facilities.

3 Data from U.S. Department of Agriculture, National Restaurant Association, and U.S. Census Bureau.

III. CHANGES AND CHALLENGES

Current trends in the food industry promise better nutrition and wider choices for consumers. At the same time, multiple factors pose challenges. These include changing food production technology, patterns of human demographics and behavior, business practices, new threats, and communication issues.

Trends in Demographics and Consumption

Changes in demographics and consumption have increased consumers' susceptibility to foodborne illness. For example, by 2015, it is estimated that 20 percent of the population will be 60 or older. Older Americans are among those at highest risk for foodborne illness.

Also, the practice of a family buying a head of lettuce and preparing a salad at home is not as common. Increasingly, consumers want the convenience of opening up a bag of salad that's already prepared, and immediately serving it.

Increasingly, consumers want the convenience of opening up a bag of salad that's already prepared, and immediately serving it.

It used to be that when a single head of lettuce was contaminated, the resulting illness affected one family. Now, contaminated heads of lettuce may be processed with thousands of other heads of lettuce and placed into bags of convenience salad that many consumers can buy. These bags of salad end up in thousands of homes, potentially resulting in hundreds of illnesses.

The shifting demographics have increased the numbers of susceptible consumers, and the convenience factors have meant that small problems can lead to large outbreaks–both indications of the need to make changes to ensure a continued high level of food protection.

Shifting Demographics

Our population demographics are changing. Shifting demographics means that more of the U.S. population is, and increasingly will be, susceptible to foodborne illness.

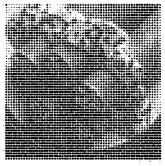
- In 2007, 20-25 percent of the population is in a high-risk category (young, older, pregnant, immune-compromised). These Americans face a risk of serious illness or death from foodborne illness*.
- In 1980, 15 percent of the population was 60 or older. By 2025, the number will be 25 percent.
- Four percent of the population is immune-compromised (transplant patients, people who are HIV positive, people receiving chemotherapy or other immunosuppressive treatments, people with chronic diseases).

** For example in a joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) report on Listeria monocytogenes (LM) microbiological risk assessment, it was estimated that transplant patients had a 2,584 increased probability of becoming ill from LM, compared with a healthy adult less than 65 years old. The same report indicated that AIDS patients had an 865-fold increase and an otherwise healthy adult over the age of 65 had a 7.5-fold increase [ftp://ftp.fao.org/docrep/fao/007/y5394e/y5394e00.pdf].*

Convenience Trends

Americans are consuming more convenience foods. Foods prepared outside the home may be subject to cross-contamination from other foods, as well as contamination from food workers.

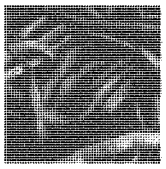
- Ready-to-eat foods (bagged salad, cut fruit) and prepared foods (including hot bars with main and side dishes, as well as salad bars) and frozen dishes that can be cooked quickly are increasing in popularity.
- Cooking in the home is decreasing—people are eating out and bringing prepared foods home.
- Spending on foodservice items, such as supermarket deli foods, accounts for about half of all U.S. food spending.



Consumption Patterns

A greater variety of foods are eaten year round. Also, foods that are consumed raw or with minimal processing are often associated with foodborne illness.

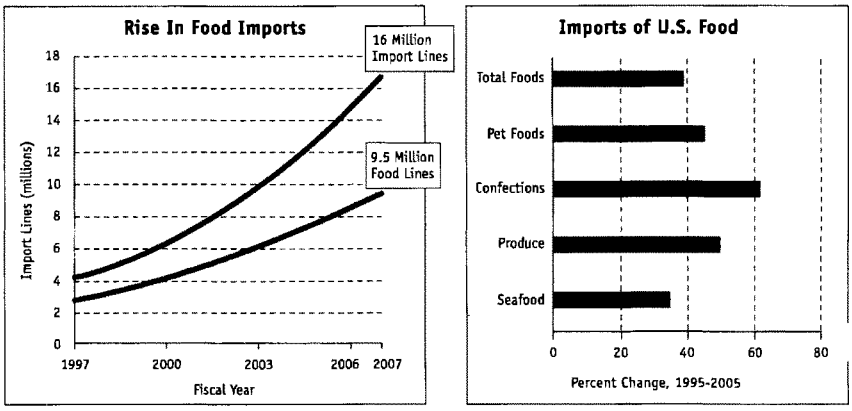
- Consumers are encouraged to make healthier food choices and increase consumption of fruits and vegetables (5-9 servings/day), including fresh produce.
- U.S. per capita consumption of fresh fruit and vegetables increased 36 percent from 1981 to 2000.
- A typical grocery store carried 173 produce items in 1987 and now carries 558 produce items.
- Produce items that were once considered seasonal are available on a year-round basis.
- Increased consumption of exotic foods whose safety hazards are not well understood.



Sources: U.S. Census Bureau and USDA Economic Research Service

Global Food Supply

There have been dramatic changes in the volume, variety, and complexity of FDA-regulated products arriving at U.S. ports. The United States trades with over 150 countries/territories with products coming into over 300 U.S. ports. In the last decade, the number of food entry lines[1] has tripled. According to the USDA Economic Research Service, approximately 15 percent of the overall U.S. food supply by volume is imported. However, in certain food categories a much higher percentage is imported. For example, approximately 60 percent of fresh fruits and vegetables consumed in the U.S. are imported, which fills the gap when U.S. domestic production is inadequate or out of season (e.g., bananas, tropical fruits, etc.). Imports of seafood rose from less than 50 percent of U.S. seafood consumption in 1980 to more than 75 percent today.



The type of imported foods is changing. In the past, the bulk of FDA-regulated imports consisted of unprocessed food ingredients with subsequent processing of those ingredients covered by FDA domestic regulatory oversight. Today, foods that are inherently more likely to pose risks, such as ready-to-eat food products, fresh produce and seafood, account for an increasing proportion of imported foods.

This is not to suggest that food imported into the United States, as a whole, poses a greater food safety risk than domestically produced food. But increases in the volume and complexity of imported foods have taxed the limits of FDA's approach to handling imports. Currently, data on 100 percent of the shipments are submitted through the electronic systems of the U.S. Customs and Border Protection (CBP) and FDA. The data are screened electronically to determine whether the food appears to present a significant risk to public health. Some foods are then inspected physically based on perceived risk. Food products of greater concern are physically inspected more frequently.

Currently, FDA often has very limited information regarding conditions under which most food is produced in foreign countries. While many foreign countries have well-developed regulatory systems to ensure food safety, other countries have systems that are less well-developed and that may not be able to ensure food safety to the same degree.

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1 An entry line means each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately.

Growth in Foreign Manufacturers Exporting Low-Acid Canned Foods		
	1973	**2004**
Domestic LACF/AF Firms	742	1,300
Foreign LACF/AF Firms	34	6,700

One example of how the source of food has changed is in the import of canned or sealed fruits, vegetables, fish, and other products (collectively known as low-acid canned food/acidified food or LACF/AF). As the table shows, the number of domestic firms nearly doubled between 1973 and 2004. By contrast, there was close to a 200-fold increase in the number of foreign firms manufacturing these products for importation into the United States during the same period.

New Threats

New Foodborne Pathogens

Symptoms of foodborne illness range from mild stomach discomfort to life-threatening neurologic, liver, and kidney syndromes. In 1999, the CDC estimated that there were around 76 million cases per year of illness from foodborne agents, with 325,000 hospitalizations and 5,000 deaths in the United States each year. These data do not identify exactly how many are spread via foods (as opposed to person-to person contact or by some other means) nor do they indicate how the food became contaminated. However, we know that the most severe cases tend to occur in people who are very young, very old, or who have compromised immune systems.

Foodborne illnesses are caused by more than 200 different foodborne pathogens (agents that can cause illness) of which we are currently aware. These include viruses, bacteria, parasites, and toxins, plus a vast number of potential chemical contaminants and metals. The variety of agents associated with foodborne illness has steadily grown over the last few decades, and there is every probability that this list will continue to increase.

One example of a newer foodborne pathogen is *Enterobacter sakazakii*, which can cause serious illness such as sepsis (blood infection) and meningitis (inflammation of the membrane surrounding the brain and spinal cord). In 2002, FDA, working with CDC, discovered and subsequently alerted health care professionals to clusters of *E. sakazakii* infections reported in a variety of locations among hospitalized newborns, particularly premature or other immuno-compromised infants who were fed powdered infant formulas.

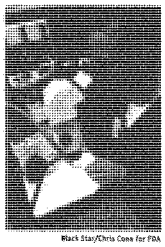
The emergence of new foodborne pathogens requires updated technologies that can detect the presence of new agents in a variety of foods. Addressing these emerging hazards requires cooperation among industry, academia, and government to share information and establish testing protocols.

Pathogens Newly Associated with Foodborne Illness Since the Mid-1970's	
• *Campylobacter jejuni*	• *Campylobacter fetus*
• *Cryptosporidium parvum*	• *Cyclospora cayetanesis*
• Shiga toxin-producing *E. coli*	• *Listeria monocytogenes*
• Noroviruses	• *Salmonella* Enteritidis
• *Salmonella* Typhimurium DT104	• *Vibrio vulnificus*
• *Vibrio cholerae* 0139	• *Yersinia enteracolitica*
• *Vibrio parahaemolyticus*	• *Enterobacter sakazakii*

Intentional Contamination
We must also consider food as a potential vehicle for intentional contamination. Such intentional contamination of food could result in human or animal illnesses and deaths, as well as economic losses.

The stark possibilities are suggested by the recent incident in which vegetable protein products, which were represented as wheat gluten and rice protein concentrate, were contaminated with melamine and melamine analogues. Though not considered an act of terrorism, the incident appeared to be a deliberate act for economic gain. It resulted in the sickness and deaths of cats and dogs, the recall of hundreds of brands of pet food products, state quarantine or voluntary holds on livestock that consumed suspect animal feed, and concern regarding the possible associated human health risks.

FDA has no reason to believe any physical harm was intended, but the melamine event indicates the danger of attempts to deliberately compromise the U.S. food system.


Black Star/Chris Cone for FDA

A scientist at FDA's Forensic Chemistry Center examines wheat gluten for possible melamine contamination.

Communication
Effective communication requires active collection and use of incoming information and timely communication to external groups. FDA uses the information it receives to make appropriate decisions about food safety. FDA also shares information and advice with consumers, news media, industry, and state, local, and foreign agencies. Providing information that is timely, useful, and easy to understand is critical.

FDA, states, and industry receive food safety information in various ways. Signals of potential problems come in the form of consumer complaints, inspection data, positive test results, adverse event reports, and other reports of illness. FDA is committed to improving information flow to improve detection and response to signs of trouble.

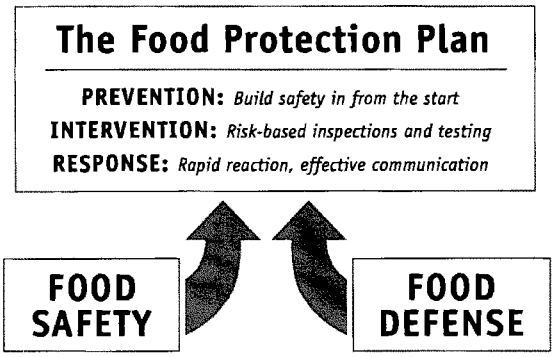
FDA collects data from several sources. Data from the testing of food, inspections, and reports of illnesses are collected in federal and state systems. Data from foodborne illness and pathogen identification are entered into systems maintained by the CDC, the lead federal agency for conducting disease surveillance and outbreak investigations. Data from imports are entered into specific import systems. Currently, states conduct 10,000 inspections under contract to FDA and another 40,000 inspections under state law. These inspections include the collection of 300,000 food samples each year.

Enabling FDA's information systems to communicate more effectively with internal and external data sources is essential. This will increase productivity of FDA staff and streamline response times during food emergencies. The overall success of the Plan depends on improving the integration and analysis of the vast amount of information collected.

Just as consumers and businesses have important roles to play in providing information to FDA, the FDA plans to improve communication with stakeholders during food emergencies. In the 2007 outbreak involving chili sauce contaminated with *Clostridium botulinum*, the recalled product remained on the shelves of small retailers weeks after the recall announcement. Improving outreach to all segments of the food industry will ensure that harmful products are removed from the market quickly.

IV. AN OVERVIEW OF THE APPROACH

Core Elements
While American consumers enjoy one of the safest food supplies in the world, growing challenges require a new approach to food protection at FDA—an increased emphasis on prevention.



Greater attention to prevention requires closer interaction with growers, manufacturers, distributors, retailers, food service providers, and importers.

Recent outbreaks linked to fresh produce, peanut butter, and pet foods show how FDA responds quickly to contain food safety problems. While this level of response needs to be maintained and even enhanced, there is also a need to focus more on building safety into products right from the start to meet the challenges of today. The FDA will work with the private sector to build on the actions of the food industry to ensure product safety. Building safety into products is described in one word: ***prevention.***

This shift to an increased emphasis on prevention is at the core of FDA's Food Protection Plan, and will be evident immediately as the FDA begins an industry-wide effort to focus attention on prevention, from general best practices for all foods to the possibility of additional measures for high-risk foods. ***Prevention*** needs to be augmented by targeted ***intervention*** that focuses inspection and testing on the areas of greatest risk. This will reduce the likelihood that contaminated products will reach consumers. However, even the best system in the world cannot prevent all incidents of foodborne illness. Along with prevention and intervention, faster and more focused ***response*** is needed once a problem is detected.

Prevention – Build safety in from the start.
FDA must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. This will require close interaction with growers, manufacturers, distributors, retailers and food service providers, and importers. These partners have the ability to implement preventive approaches and to require them of their suppliers. FDA will continue to work with industry, state, local, and foreign governments to further develop the tools and science needed to identify vulnerabilities and determine the most effective approaches. With regard to imports, FDA will also work with foreign governments, which have a greater ability to oversee manufacturers within their borders to ensure compliance with safety standards.

Intervention – Verify prevention and intervene when risks are identified.
FDA, along with other federal agencies and state, local, and foreign governments, must undertake interventions in a coordinated and risk-based manner. Interventions, in the form of targeted inspections and testing, verify that preventive controls are working and that resources are being applied to the areas of greatest concern—either when the product is at the manufacturing facility, on its way to stores, or at a port of entry. Successful intervention will also require enhanced risk analysis, along with new detection technology to allow for faster analysis of samples. A successful and fully integrated food protection system will identify signals that indicate the need for intervention. Such signals may be a positive test for a harmful contaminant following an inspection, an industry report, a consumer complaint, or a full blown outbreak.

***Response** – Respond rapidly and appropriately.*
Working with its food safety partners, FDA will improve its response system to more rapidly react when signals indicate either potential or actual harm to consumers. As part of an improved response system, the FDA will develop faster and more comprehensive ways to communicate with consumers and others during a food-related emergency.

Cross-Cutting Principles

Four important cross-cutting principles will allow a comprehensive food protection approach along the entire production chain.

Principles of the Food Protection Plan

1. Focus on risks over a product's life cycle from production to consumption.
2. Target resources to achieve maximum risk reduction.
3. Address both unintentional and deliberate contamination.
4. Use science and modern technology systems.

1. Focus on risks over a product's life cycle from production to consumption.

Comprehensive food protection requires considering the safety and defense risks associated with foods through their whole life cycle whether domestically produced or imported. Consideration must be given to areas that are potentially vulnerable to both unintentional and intentional contamination such as the point at which food is grown or produced, every processing or manufacturing step, points involved in distribution, transport, and warehousing, as well as all the points at the retail level through distribution to consumers. It is also important to consider the role that consumers play in safeguarding food once it is in their homes.

Consideration of the risks throughout a product's life cycle is a significant shift in the Agency's approach not only for domestic products but for imported foods too. A focus on prevention at the point of manufacture based on risk will provide data to strengthen risk-based inspections domestically, at the border, and overseas. In particular, FDA plans to work with foreign governments and federal partners to ensure that foods produced in foreign facilities meet U.S. safety requirements. Risk-based targeted inspections at the border will serve as a second layer of protection, rather than the principal one.

2. Target resources to achieve maximum risk reduction.

A comprehensive risk-based approach must consider the many variables that define risk. Such variables include:

- the possibility that consuming a particular food will result in a foodborne illness due to contamination of the product, which depends on such factors as the number of microbes present or the level of a chemical or toxin present, the susceptibility of the person to the contaminating agent, and whether the food was properly handled and cooked;
- the severity of that illness, should it occur;
- the point in the production cycle where contamination is most likely to occur; and
- the likelihood of contamination and steps taken during the production cycle to reduce the possibility of contamination

Foodborne illnesses range from distressing, but tolerable, symptoms to critical and life-threatening health problems. Illness due to *E. coli* O157:H7 can lead to kidney failure. Exposure to botulinum toxin can cause paralysis. Other, less severe illnesses may cause diarrhea and vomiting.

Some foods, such as those grown in the ground, may have little or no processing before they arrive in consumers' homes. Other foods are cooked to high temperatures (e.g., canned goods). Examining all aspects of the product life cycle helps define the areas of greatest risk. Implementation of the Plan will involve acquiring the data to best address risk, or, where the data is unavailable, working with appropriate partners to determine those risks.

3. Address both unintentional and deliberate contamination.

Food safety, which traditionally refers to unintentional contamination, has been a cornerstone of public health for many years. The idea that someone may use food as a vehicle to deliberately cause harm is a risk that must be addressed. There is a heightened awareness of terrorism as a real possibility that could cause a major public health crisis. To this end, FDA has devoted significant efforts over the last six years to address food defense—defending the food supply against deliberate attack.

Whether dealing with intentional or unintentional contamination, the same regulatory experts, resources, and industry partners are involved. The best way to handle food safety and food defense is to develop approaches that appropriately address both. Although there are differences in how these events are addressed, there are also many overlaps and parallels between the two. For example, the concepts of prevention, intervention, and response apply equally to both.

Those at highest risk for serious foodborne illness include young children, older adults, pregnant women, and people with weakened immune systems.

4. Use science and modern technology systems.

A successful plan for food protection is based on science. FDA's Food Protection Plan emphasizes the need to know the science underpinning how and where food becomes contaminated and the associated risks. The Plan also highlights the use of science to determine optimal interventions to reduce the likelihood of contamination. If contamination does occur, then the priority is to minimize the likelihood that it will cause significant harm. For example, successful intervention relies in large part on the science of epidemiology to understand which foods pose risks and the science of modern detection methods to identify harmful agents quickly.

The Food Protection Plan also highlights the need to further integrate information systems. Too often, sophisticated data systems lack the ability to share information. A priority in the Plan involves creating interoperable data systems, along with making current systems more interoperable, to allow for the exchange of product information along the whole life cycle. The goal is to make the most of important data from all relevant systems, and to obtain easier access to critical information.

V. THE INTEGRATED PLAN

The Food Protection Plan is based on three integrated elements of protection:

1. ***Preventing*** foodborne illnesses in the first place;
2. ***Intervening*** with risk-based FDA actions at critical points in the food supply chain; and
3. ***Responding*** rapidly when contaminated food or feed is detected.

Implementation of the elements will begin immediately, be phased in over time, and be integrated with the Administration's Import Safety Action Plan. All of the elements build on existing partnerships and direct resources to the areas of greatest risk.

But the FDA cannot take some key actions without new legislative authority. We summarize below in each element the new authorities needed to fully implement the Plan and strengthen

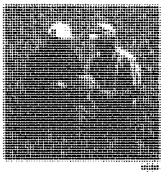
our ability to protect Americans. We look forward to working productively with Congress to ensure understanding of the design of and need for these authorities.

CORE ELEMENT #1: PREVENTION

Prevention is the first essential step for an effective, proactive food safety and defense plan. FDA's Plan implements three key prevention steps, which will move forward concurrently. The prevention steps are risk-based and will be implemented as appropriate to particular segments of the industry, taking into account that some foods are inherently safer than others.

The Plan's Key Prevention Steps

1. Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses
2. Identify Food Vulnerabilities and Assess Risks
3. Expand the Understanding and Use of Effective Mitigation Measures



The Food Protection Plan builds on partnerships and directs resources to the areas of greatest risk.

FDA designed its Plan for the full life cycle of food—from production to consumption whether it be domestic or imported. The prevention elements of the Plan emphasize the importance for FDA and corporations to work collaboratively to prevent food problems from occurring.

This will be accomplished through a comprehensive review of food supply vulnerabilities. FDA will work with industry and other stakeholders to develop effective tools and science to head off outbreaks of foodborne illness caused by unintentional and intentional factors.

Some examples of enhanced corporate responsibility might include:
- evaluating safety and security vulnerabilities and possible impacts
- when appropriate, implementing preventive measures—both required and voluntary—to ensure that food is produced safely and securely
- developing a contingency plan to aid in a response in the event of contamination

1.1 Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses

Strengthen FDA Actions

- Meet with states and consumer groups to solicit their input on implementing preventive approaches to protect the food supply.
- Meet with food industry representatives to strengthen science-based voluntary prevention efforts, including developing best business practices and food safety guidelines.
- Develop written food protection guidelines for industry to a) develop food protection plans for produce and other food products, and b) implement other measures to promote corporate responsibility.
- Issue in Spring 2008, a final regulation requiring measures to prevent *salmonella* in shell eggs and resulting illnesses.
- Meet with foreign governments to share results of domestic prevention efforts and develop approaches for improving food safety at the source.
- Provide foreign countries with technical assistance so that they can enhance their regulatory systems.
- Analyze food import trend data and integrate it into a risk-based approach that focuses inspection resources on those imports that pose the greatest risk.
- Focus foreign inspections on high-risk firms and products.
- Improve FDA's presence overseas.

Additional Legislative Authority Needed

Allow FDA to Require Preventive Controls Against Intentional Adulteration by Terrorists or Criminals at Points of High Vulnerability in the Food Chain

The FDA requests authority to require entities in the food supply chain to implement measures solely intended to protect against the intentional adulteration of food by terrorists or criminals. This authority would allow FDA to issue regulations requiring companies to implement practical food defense measures at specific points in the food supply chain where intentional contamination has the greatest potential to cause serious harm, such as requiring locks on tanker trucks transporting food. The specific points would be determined using vulnerability assessments such as CARVER+Shock[1], and the authority would only apply to food in bulk or batch form, prior to being packaged, which have clearly demonstrated vulnerabilities (e.g., short shelf life), and where it would affect multiple servings and there is a high likelihood of serious adverse health consequences or death from intentional adulteration. These regulations will be developed, taking into account the best available understanding of the uncertainties, risks, costs, and benefits associated with alternative options. The requirement would utilize industry best practices and would not apply to raw produce or food on farms, except for milk. FDA also proposes that firms be extended an affirmative defense in civil litigation if they comply with these controls.

Authorize FDA to Issue Additional Preventive Controls for High-Risk Foods

The FDA requests explicit authority to issue regulations requiring specific types of foods (those that have been associated with repeated instances of serious health problems or death to humans or animals from unintentional contamination) be prepared, packed, and held under a system of preventive food safety controls. Such authority would strengthen the FDA's ability to require manufacturers to implement risk-based Hazard Analysis and Critical Control Point (HACCP) or equivalent processes to reduce foodborne illnesses from high-risk foods.

Require Food Facilities to Renew Their FDA Registrations Every Two Years, and Allow FDA to Modify the Registration Categories

FDA requests statutory changes that would require facilities to register every two years and authorize the FDA to establish food categories within the registration system. These categories would allow FDA to tailor registration categories based on up-to-date food safety information. Under current law, FDA must use preexisting food categories that were not designed for registration purposes and therefore are of limited usefulness for evaluating potential threats to food protection. This change would ensure accurate, up-to-date registration data from facilities. Facilities whose registration remains unchanged would be able to file a simplified renewal registration or affirmation to that effect.

[1]*The CARVER+Shock model, explained in detail at http://www.cfsan.fda.gov/~dms/vltcarv.html, stands for Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognizability, plus Shock. It is available as a software tool to evaluate the potential vulnerabilities of farm-to-table supply chains of various food commodities, as well as individual facilities or processes.*

Why These Actions Are Important and What They Will Accomplish

Those with the biggest stake in food safety, after the consumers who eat the food, are the people and companies who grow, process, and sell food. Their livelihood depends entirely on the confidence of their customers. A poor reputation for proper food handling can drive a company to bankruptcy. Promoting increased corporate responsibility is key in shifting FDA's food protection effort to a proactive rather than a reactive one. The FDA will seek partnerships with industry to enhance consumer confidence. FDA will continue to work with industry in a) developing food protection plans that address safety and defense vulnerabilities, b) implementing prevention steps, and c) developing contingency plans to improve response to an outbreak of foodborne illness.

The FDA will primarily focus on promoting the use of risk-based, preventive systems that companies can apply at all levels of food production and processing, when appropriate. Voluntary approaches may be as basic as good manufacturing practices to ensure proper equipment sanitation and employee safety training. Potentially high-hazard food categories may require additional control measures. FDA will work with industry, consumer, and federal, state, local, and international partners to help model and promote preventive controls based on best industry practices.

FDA plans to acquire additional data to develop a better understanding of foreign country practices for food and feed. This may include the examination of best practices around the food safety control systems of other countries as well as increased understanding of the difficulties faced in implementing food protection measures. FDA will also seek to share U.S. food safety and defense best practices with foreign governments and provide technical assistance, when possible, to those countries exporting food products to the U.S. so they can enhance their regulatory systems. As part of its review of foreign systems and products, the Agency will analyze food import trend data and integrate it into a risk-based approach that focuses inspection resources on those imports that pose the greatest risk. This approach will also focus foreign inspections on high-risk firms. In the near term, a special emphasis will be placed on firms located in countries where imports into the United States have been refused repeatedly and import violations have threatened the health of U.S. consumers.

FDA's current and planned actions, along with the proposed legislative changes, would:
- Build safety and defense into the full food product life cycle–from production to consumption.
- Support work with industry, and state, local, and foreign governments to understand industry best practices and identify how and where preventive controls would work best.
- Promote the adoption of voluntary preventive controls throughout the food supply chain.
- Enhance relationships with trading partners and improve FDA's presence abroad.

1.2 Identify Food Vulnerabilities and Assess Risks

Strengthen FDA Actions
- Work with the food industry, consumer groups, and federal, state, local and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities.
- Use enhanced modeling capability, scientific data, and technical expertise to evaluate and prioritize the relative risks of specific food and animal feed agents that may be harmful.
- Establish a risk-based process to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease.
- Work with CDC to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated.

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish
These FDA actions provide important tools to facilitate increased corporate responsibility to prevent food contamination. These actions also address the need for additional information to better understand food safety and defense vulnerabilities and possible impacts. FDA will continue its work in this area and further engage industry and other outside groups to identify and target the greatest risks.

FDA actions will include gathering data for risk assessments and to conduct risk evaluations of commodity-agent combinations and relative risk ranking of commodities. A comprehensive, risk-based approach allows the FDA to maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health.

By analyzing data collected throughout the food product life cycle, we are better able to detect risks posed by food products. We are also better able to recognize key junctures where timely intervention can reduce or avoid those risks. Working with CDC, FDA will also build the capacity to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated.

Once established and emerging risks have been identified, assessed, and ranked, we can more effectively allocate our available resources to manage these risks as addressed below.

FDA's current and planned actions would:
- Strengthen the FDA's risk assessment capabilities and capacity to provide risk evaluations efficiently and rapidly.
- Advance collaborative work with CDC, USDA, and other federal, state and local agencies to understand attribution data on the food commodities that cause foodborne illnesses.

CORE ELEMENT #1: PREVENTION continued

1.3 Expand the Understanding and Use of Effective Mitigation Measures

Strengthen FDA Actions
- Focusing on higher-risk foods, develop and implement a basic research plan on sources of contamination, modes of spreading and best methods to prevent contamination.
- Research, evaluate, and develop new methods to detect food contaminants.
- Encourage outside development of new contamination detection and prevention technologies.
- Develop Web sites and other platforms for disseminating research results and new steps industry can use to address vulnerabilities.

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish
Building on risk assessments, FDA will initiate basic research to enhance our understanding of sources of contamination, modes of spreading, and how best to prevent contamination. This information in turn will inform FDA's efforts above to promote increased corporate responsibility to implement effective preventive steps.

Focusing on higher-risk foods, FDA—working with other agencies—will undertake basic research and leverage relationships with outside organizations. The FDA will also research, evaluate, and develop new methods to detect contaminants in foods, and seek to facilitate new technologies that enhance food safety.

FDA's current and planned actions would:
- Initiate risk-driven research about sources, spread and prevention of contamination.
- Develop new mitigation tools and implement appropriate risk management strategies.

CORE ELEMENT #2: INTERVENTION

Because no plan will prevent 100 percent of food contamination, we must have targeted, risk-based interventions to provide a second layer of protection. These interventions must ensure that the preventive measures called for are implemented correctly. These interventions must also identify contaminated food that either unintentionally or intentionally circumvent our prevention plan. The Plan includes three key intervention steps.

The Plan's Key Intervention Steps
1. Focus Inspections and Sampling Based on Risk
2. Enhance Risk-Based Surveillance
3. Improve the Detection of Food System "Signals" that Indicate Contamination

These steps emphasize targeted interventions at the point of manufacture and during distribution. They allow FDA to safeguard domestic products while increasing protection against importation of unsafe food.

Using robust risk-based analysis, FDA will conduct high-priority inspections that rely on statistical sampling and advanced risk detection tools. The FDA will verify industry busi-

ness practices across the food chain to ensure that effective preventive measures are in place. Gathering and analyzing test results, adverse event reports, consumer complaints, and other information will help the FDA track emerging food protection problems.

CORE ELEMENT #2: INTERVENTION continued

2.1 Focus Inspections and Sampling Based on Risk

Strengthen FDA Actions

- Focus food and feed safety inspections and sampling based on risk.
- Identify, evaluate and, if appropriate, validate and implement innovative foodborne pathogen detection methods and tools capable of quickly and accurately detecting contaminants in foods, such as real-time diagnostic instruments and methods that allow for rapid, on-site analysis of a particular sample.
- Train FDA and state investigators on new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment, and modern inspection strategies.
- Collaborate with foreign authorities to reduce potential risk of imported food.

Additional Legislative Authority Needed

Authorize FDA to Accredit Highly Qualified Third Parties for Food Inspections

The universe of domestic and foreign food establishments subject to FDA inspection is immense and continuing to grow faster than the FDA's inspection resources. Even with the most sophisticated detection tools and laboratory capabilities, the FDA's inspection resources are finite. Therefore, legislation to authorize the FDA to accredit independent third parties, or to recognize entities that accredit, to evaluate compliance with FDA requirements would allow FDA to allocate inspection resources more effectively.

To establish such an accreditation program for voluntary food inspections, FDA would undertake a public process to determine best practices and solicit industry input in the design of the program. An FDA accreditation program would require FDA to accredit third-party organizations, or recognize an entity that accredits third parties. Third-party organizations could be, as appropriate, federal departments and agencies, state and local government agencies, foreign government agencies, or private entities without financial conflicts of interest. FDA would also:

- *Audit the work of these organizations to ensure that FDA requirements were consistently assessed;*
- *Review their inspection reports; and*
- *Provide ongoing training criteria to ensure they maintain their skills and knowledge, especially as technology and requirements change over time.*

FDA would use information from these accredited third-party organizations in its decision making but not be bound by such information in determining compliance with FDA requirements. Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. Use of accredited third parties may also be taken into consideration by the FDA when setting inspection and surveillance priorities.

Require New Reinspection Fee From Facilities That Fail to Meet Current Good Manufacturing Practices (cGMPs)

As part of the 2008 budget process, the Administration proposed a new user fee requiring manufacturers and laboratories to pay the full costs of reinspections and associated follow-up work when FDA reinspects facilities due to failure to meet cGMPs or other FDA requirements. Where FDA identifies violations during an inspection or issues a warning letter, FDA conducts follow-up inspections to verify a firm's corrective action. The proposed reinspection fee ensures that facilities not complying with health and safety standards bear the cost of reinspection.

Why These Actions Are Important and What They Will Accomplish

Effective FDA intervention means getting product risk information quickly to FDA investigators who oversee the regulated products, including a high volume of import entries. This information will allow the FDA to make better-informed decisions about what products

should be examined more closely and tested. It also signals when to initiate further action such as additional surveillance or an enforcement action.

CORE ELEMENT #2: INTERVENTION continued

FDA will look to leverage the resources of outside parties to accomplish more in-depth review of food products. By improving product knowledge and communication with all of our partners, including foreign authorities and the import community, we also can identify lower-risk products requiring less FDA scrutiny at U.S. facilities and at the border. This would enable the FDA to shift more resources to evaluating more closely products that are more risky, less well known, or from unknown manufacturers.

Modern detection tools and methods are critical for effective inspections and sampling. Better detection tools will allow FDA and other partners involved in food testing to more quickly and accurately detect contaminants. Because of its relevant expertise and experience, the FDA has unique capabilities to develop these tools.

Such tools could include real-time diagnostic instruments and methods that allow for rapid, on-site analysis of a particular sample or entry, especially those that are considered high-risk. For example, rapid contamination detection technology could be expanded to cover new agents and new food types, such as produce and dairy products. This type of technology could reduce analysis time from days to minutes. Increasing the speed at which the FDA can detect problems will allow FDA to expedite import entry review decisions or provide critical health information to the public when a problem is identified.

In addition to modernizing detection tools using information technology, the FDA must modernize inspectional strategies. This means increasing the probability that investigators will observe and identify potential problems.

FDA's current and planned actions, along with the proposed legislative changes, would result in:
- Focused risk-based inspections and sampling across the food chain.
- Development of rapid detection and testing tools.
- Increased involvement of federal, state, local, and foreign governments, in coordination with other food safety partners.
- Greater product knowledge and oversight through the accreditation of independent third parties.
- Modernized inspectional strategies.

2.2 Enhance Risk-based Surveillance

Strengthen FDA Actions
- Further enhance FDA's ability to target imported foods for inspection based on risk and publish the *Prior Notice of Imported Foods* Final Rule in 2008 as part of Bioterrorism Act implementation.
- Conduct foreign food and animal feed inspections more efficiently using the tools designed to target high-risk firms.
- Use advanced screening technology at the border.
- Improve data quality and handling capacity for food imports.
- Enhance information sharing agreements with key foreign countries.

Additional Legislative Authority Needed

Authorize FDA to Require Electronic Import Certificates for Shipments of Designated High-Risk Products

For food imports, the burden falls primarily on FDA to inspect and detect contamination at the U.S. border. With the explosion in import volume, this burden has become a serious challenge. The FDA should have

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the option of moving the inspection of high-risk products of concern "upstream" by entering into agreements with the exporting country's regulatory authority for that authority (or an FDA-recognized third-party inspector) to certify each shipment or class of shipments for compliance with FDA's standards prior to shipment. FDA would apply this requirement for imported products that have been shown to pose a threat to public health for U.S. consumers and thus would be unlike other imports where there is no such showing of risk. Such import certificate programs would be used for designated products imported from countries with whom FDA has concluded an agreement on a certification program that provides a level of safety sufficient to meet HHS/FDA standards. FDA would implement the government-to-government agreement by requiring importers to provide certificates from either relevant government agencies or accredited third parties.

While FDA would retain the authority to verify the safety of imported products, this approach shares the burden of ensuring the safety of food products with the exporting country. Shipments that fail to meet requirements would be refused entry.

For such a system to be effective, FDA will have to establish an in-depth collaboration with the relevant foreign government authority to ensure that the standards, processes, and criteria the foreign authority or third party uses in certifying products are sufficient to ensure compliance with FDA food safety standards. The FDA will also have to take several steps to ensure a secure system that prevents counterfeiting of the certificates and takes into consideration transshipment of products as a way to avoid certification.

FDA would use non-discriminatory science and risk-based criteria to determine the focus of this proposed authority and would use the authority only to the extent necessary to protect human or animal life or health.

Require New Food and Animal Feed Export Certification Fee to Improve the Ability of U.S. Firms to Export Their Products

As part of the 2008 budget process, the Administration proposed a new export certification fee for the issuance of export certificates for foods and feeds to those situations where exportation is restricted without this type of certificate. Private sector exporters would bear the cost of the program, but would reap its benefits through the FDA's enhanced ability to facilitate product exports. Importantly, collection of these user fees will enable the FDA to issue certificates without redirecting resources from other critical food and animal feed safety programs devoted to protecting the public health. Such fees are currently collected by the FDA for export certificates for drugs and devices.

Provide Parity Between Domestic and Imported Foods if FDA Inspection Access is Delayed, Limited, or Denied

While FDA currently has the authority to obtain a warrant or initiate criminal proceedings if it is denied access to inspect facilities here in the U.S., its ability, under the Federal Food, Drug & Cosmetic Act, to enforce the inspection provisions for overseas sites is very limited. In particular, the FDA cannot refuse admission of food, even if its efforts to conduct a foreign inspection were unduly delayed, limited or denied at a facility where the product was manufactured, processed, packed or held. Having the authority to prevent entry of food from firms that fail to provide FDA access will enable the FDA to keep possibly unsafe food from entering U.S. markets. This authority provides strong motivation for firms to allow FDA to perform inspections, motivation similar to that provided to domestic firms. The authority would include several procedural safeguards, including an informal hearing if food is refused admission into the United States, such as is available for food that may be refused entry for other reasons.

CORE ELEMENT #2: INTERVENTION continued

Sampling the highest priority imports, especially those posing a significant public health threat, is critical ...

Why These Actions Are Important and What They Will Accomplish

FDA must prevent products that pose food safety and food defense threats from entering the United States. A targeted, risk-based approach to foreign product regulation is essential. Sampling the highest priority imports, especially those posing a significant public health threat, is critical and dependent on data related to the practices in the foreign facility. The activity will enhance FDA's import programs and focus these programs on the life cycle of the imported product, through such means as enhanced use of information-sharing agreements with key foreign countries.

In addition, FDA will continue to look for enhanced ways to use risk-based screening technology to identify products that pose health risks at the border. For example, a screening technology prototype is currently being tested on imported seafood products in Los Angeles. If demonstrated successful, this technology could be extended to other imported products

and ports, thus enhancing the FDA's ability to quickly screen products at the border.

FDA's current and planned actions, along with the proposed legislative changes, would:
- Better focus on the imported products' total life cycle.
- Improve data systems to monitor foreign-produced food products.

CORE ELEMENT #2: INTERVENTION continued

2.3 Improve the Detection of Food System "Signals" that Indicate Contamination

Strengthen FDA Actions

- Deploy new rapid screening tools and methods to identify pathogens and other contaminants.
- Improve FDA's adverse event and consumer complaint reporting systems, including capturing complaints made to food manufacturers and distributors.
- Work to create a *Reportable Food Registry* for reports of a determination that there is a reasonable probability that the use of or exposure to an article of food will cause serious harm or death to humans or animals [as defined in the 2007 Food and Drug Administration Amendments Act (FDAAA)]. Under FDAAA, industry is expected to report such situations to the FDA within 24 hours.
- Work to create an *Early Warning Surveillance and Notification System* to identify adulterated pet food products, outbreaks of pet illness and to provide notice to veterinarians and other stakeholders during pet food recalls (as defined in the 2007 Food and Drug Administration Amendments Act or FDAAA).

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish

FDA can better detect and more quickly identify risk "signals" in the food supply chain via two key approaches: 1) deploying new rapid screening tools and methods to identify pathogens and other contaminants; and 2) enhancing its ability to "map" or trace adverse events back to their causes (whether reported to FDA or the food manufacturer or distributor) by improving its adverse event and consumer complaint reporting systems. This additional information will serve as a supplemental warning indicator for trending emerging food protection problems.

To provide the information necessary to allow for early detection of, and intervention with, contaminated animal feed, FDA will develop a centralized database for veterinarians that captures data on food safety incidents and the causes of food-related illness. The FDA will populate the database with key information from the veterinary community, veterinary hospitals, and other private U.S. sources.

FDA's current and planned actions would identify:
- signals that may indicate a problem with food from routine testing, consumer complaints, industry reporting and documented illnesses.

CORE ELEMENT #3: RESPONSE

During the past year, FDA responded to food safety problems with contaminated spinach, lettuce, vegetable proteins, and peanut butter, among other foods. Whether contamination is unintentional or deliberate, there is a need to respond faster and communicate more effectively with consumers and other partners.

The following key response steps will increase FDA's ability to quickly identify food safety problems, better coordinate a rapid emergency response among FDA, state and local government response teams as appropriate, and improve communications to the public, industry and other partners. This will better protect public health, help reduce the economic hardship affected industries face, and most importantly, maintain consumer confidence in the U.S. food supply following an incident.

The Plan's Key Response Steps
1. Improve Immediate Response 2. Improve Risk Communications to the Public, Industry and Other Stakeholders

CORE ELEMENT #3: RESPONSE continued

3.1 Improve Immediate Response

Strengthen FDA Actions

- Enhance the data collection, incident reporting and emergency response mapping capabilities of FDA's Emergency Operations Network Incident Management System.
- Work with stakeholders to develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.
- Increase collaboration with foreign, federal, state, and local FDA partners to identify a contamination source, remove contaminated products, and implement corrective actions.
- Work with CDC and other selected federal, state, and local testing labs to communicate real-time testing results among FDA and lab members.

Additional Legislative Authority Needed

Empower FDA to Issue a Mandatory Recall of Food Products When Voluntary Recalls Are Not Effective

Although FDA has the authority to seize adulterated or misbranded food, this is not a practical option when contaminated product has already been distributed to hundreds or thousands of locations. And while the FDA has been able to accomplish most recalls through voluntary actions by product manufacturers or distributors, there are situations in which firms are unwilling to conduct a recall. In such situations FDA needs the ability to require a firm to conduct a recall to ensure the prompt and complete removal of food from distribution channels. This authority would be limited to foods that the Secretary has reason to believe are adulterated and present a threat of serious adverse health consequences or death. It would be imposed only if a firm refuses or unduly delays conducting a voluntary recall. An order to recall food could only be issued by the HHS Secretary, Deputy Secretary, or Commissioner of Food and Drugs, and would be accompanied by appropriate due process rights.

Provide FDA Enhanced Access to Food Records During Emergencies

During food-related emergencies, the FDA needs more complete and streamlined access to records necessary to identify the source of foodborne illness and take needed action. Improved access to information, including records related to an article of food or related articles of food that may present a threat, will enhance FDA's ability to identify problems, respond quickly and appropriately, and protect public health.

Currently, emergency access to records is limited to instances where, for an article of food, FDA has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death. FDA proposes to expand access to records of related articles of food, such as food produced on the same manufacturing line. FDA also proposes, in food-related emergencies, to remove the adulteration requirement to allow its inspectors access to records in emergency situations where FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death. The recent melamine situation in which FDA had early clinical evidence that a specific food was causing illness in pets but did not have clear evidence of a specific adulteration is an example of such a scenario.

The records access would relate only to safety or security of the food and would not apply to records pertaining to recipes, financial data, pricing data, personnel data, research data, and sales data. The requirement would not impose any new recordkeeping burdens, and would maintain the current statutory exclusions for the records of farms and restaurants.

Why These Actions Are Important and What They Will Accomplish

Recent food safety threats have demonstrated the importance of FDA's emergency response system. Contaminant tracing—or identifying where the contaminant has traveled within the food or feed supply—is critical in rapidly containing potential risks. Working with partners, FDA will pursue improvements to the current trace-back process and develop an action plan for implementing process improvements to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.

As part of that effort, FDA will work with selected federal, state, and local testing labs to communicate real-time testing results among FDA and lab members.

FDA will also increase collaboration with foreign, state, and local regulators to identify the source of contamination, remove contaminated products as quickly as possible, and implement measures needed to prevent future contamination.

These improvements will allow FDA to quickly isolate problems, prevent contaminated products from reaching consumers, and ensure targeted recalls of products. Such steps aim to minimize the public health and economic impact from an outbreak.

FDA's current and planned actions, along with the proposed legislative changes, would:
- Enhance the nation's food emergency response system.
- Expand the FDA's trace-back process.
- Improve multi-partner collaborations, including with foreign regulators.

3.2 Improve Risk Communications to the Public, Industry, and Other Stakeholders

Strengthen FDA Actions

- Work with communications and media experts, including FDA's Risk Communication Advisory Committee, to design and conduct consumer communications and behavior response studies.
- Update the Food Protection Risk Communications Plan using the most effective strategies for sharing information with consumers.
- Build a consumer Web site to communicate relevant food protection information.
- In a food-related emergency, implement this communications plan, including utilizing all relevant media and technologies to reach consumers, retailers, industry, public health officials, and other stakeholders resulting in a better informed and thus more resilient population.

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish

Consumers protect themselves and their families from foodborne illness by responding promptly to FDA alerts. Important messages must be communicated clearly and through multiple forms of media to be effective, because different segments of the population use different technologies, ranging from television and newspapers to text messages and podcasts. In addition, major segments of the population do not use English as their primary language and rely on still other sources of information. This increases the challenge of implementing effective communication strategies.

Retailers, public health officials, industry and other key stakeholders likewise use an array of communications vehicles and sources. FDA's communication strategy during emergencies must use all such media to reach these different audiences and ensure that potentially harmful products are removed promptly.

FDA will enhance its risk communication program through aggressive, targeted food safety campaigns that disseminate clear and effective messages and regular updates through multiple venues to all targeted audiences. This program's designers will solicit input from the

new FDA Risk Communications Advisory Committee, which is tasked with obtaining expert advice in the field of risk communications.

CORE ELEMENT #3: RESPONSE continued

FDA's current and planned actions will enable the FDA to:
- Communicate more effectively with consumers.
- Provide more rapid alerts to all stakeholders, including retailers, industry, public health officials, and the consumers.

VI. ENHANCE INFORMATION TECHNOLOGY

In support of all three components of the Food Protection Plan, FDA plans to enhance its IT systems related to both domestic and imported foods. The focus will be to help the FDA more rapidly identify food importers, and maintain, update, and search records on food facilities and shipments more efficiently.

In particular, FDA will enhance collaboration with CBP on IT systems to more accurately identify firms involved in the food import supply chain during the import screening and review processes. These systems will allow for analysis of historical risk data about firms when making entry decisions for the firms' products.

A new systems approach can eliminate many problems with our current data. For example, assigning a unique identifier will eliminate duplicate records and make risk data about a firm easier to access. Policies for requiring the use of the new single national identifier will need to be established and agreed upon, recognizing the impact on industry worldwide.

Nearly all FDA business processes will benefit from more reliable and accurate information. Implementation of a new system will require a coordinated multi-agency effort that will benefit all federal agencies that process imported foods. CBP's existing data and ongoing activity will play a key role.

Finally, FDA will ensure that its infrastructure and disaster recovery system for IT systems and data are ready to deal with planned (maintenance and upgrades) and unplanned outages. This will provide the necessary support for import operations, which require the availability of multiple FDA systems around the clock. As an example, shipments arrive at U.S. ports day and night, and Prior Notice data are submitted at all hours. IT systems provide screening of the data as they are submitted, and Prior Notice Center (PNC) staff work around the clock to review the risk presented by shipments before their arrival. The PNC needs to review shipment data in as little as two hours from submission. Any interruption in the availability of the computer systems prevents the filing and timely review of information. This affects the flow of goods into the United States, and poses a safety risk to consumers.

An integrated, IT infrastructure—with data gathering, sorting, mining, and trending capability built into the systems—is critical to the success of FDA's food protection efforts.

VII. CONCLUSION

Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission—to protect and promote public health. The FDA remains committed to working closely with its partners to protect the nation's food supply.

In the United States, market forces give companies a strong motivation to be vigilant and even innovative in ensuring food safety. The laws of regulation must encourage, not disrupt, these motivations. Rather than taking over responsibility from food companies, FDA wants to protect their flexibility to pursue it vigorously.

Although we have made progress, much remains to be done. Recent incidents of contaminated food and animal feed have highlighted the importance of a strong food protection system. Americans rightly expect to purchase food without having to worry about safety.

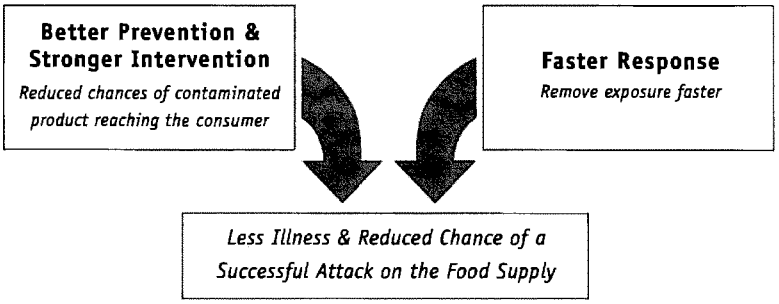
Rising food imports, increasing consumption of convenience foods, and new foodborne pathogens are among the challenges we face. To address these challenges, we must move toward a food safety and defense system that is more proactive and strategic.

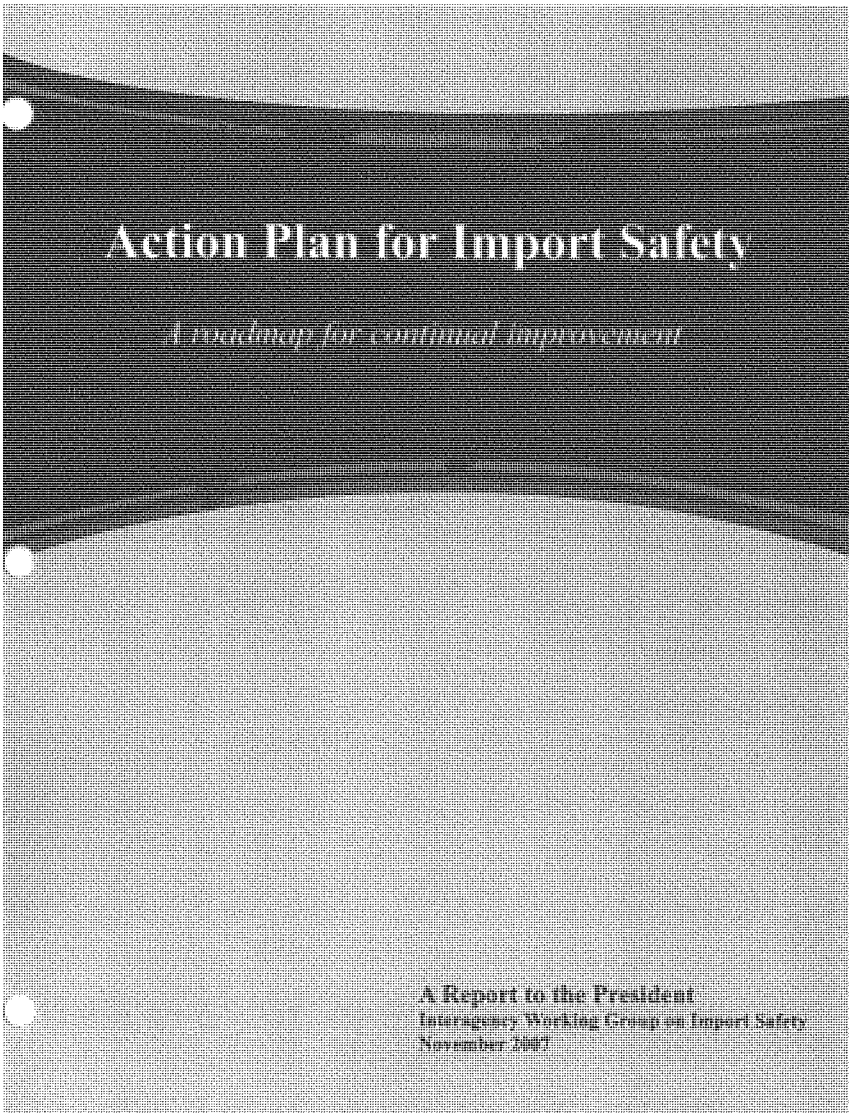
FDA's Food Protection Plan contains three core elements—prevention, intervention, and response—with greater emphasis on preventive measures that keep contaminated food from ever reaching consumers. The Plan operates through a set of integrated strategies that address the product life cycle, a risk-based allocation of resources, the integration of food safety and food defense, and builds on a foundation of science and modern information systems.

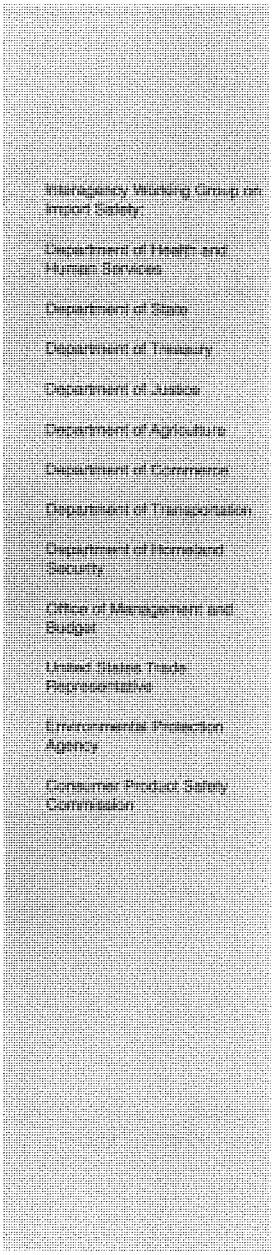
FDA's Food Protection Plan complements the nation's strategic framework for import safety, which was released by the U.S. Department of Health and Human Services in September 2007. Both plans focus efforts on working smarter and better with importers, manufacturers, and other government agencies.

FDA will aggressively pursue the Food Protection Plan so that U.S. consumers can be assured that their food remains among the safest in the world.

The Public Health Impact of the Food Protection Plan




Action Plan for Import Safety
A roadmap for continued improvement
A Report to the President
Interagency Working Group on Import Safety
November 2007



We will continually improve the safety of imported products in a manner that expands global trade and protects the health and safety of every American.

President George W. Bush

November 6, 2007

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

The Interagency Working Group on Import Safety is pleased to submit this *Action Plan for Import Safety: A roadmap for continual improvement.* In it, we detail a roadmap with short- and long-term recommendations and action steps.

This Action Plan represents the culmination of thousands of hours of research and analysis, as well as public comment received from hundreds of stakeholders. The Action Plan takes the form of 14 broad recommendations and 50 specific action steps based on *Protecting the American Consumer Every Step of the Way: A strategic framework for import safety* and the *Immediate Actions Memorandum* presented to you on September 10, 2007.

In the last two months, significant progress has been made on the Immediate Action Items listed in my memorandum to you accompanying the Strategic Framework. The Office of Management and Budget has actively engaged the departments, and all agencies are on track to accelerate their participation in the Automated Commercial Environment / International Trade Data System. In addition, the State Department has led a vigorous international outreach effort to communicate our import safety priorities with our trade partners around the world. The Office of the United States Trade Representative has moved forward with the departments and agencies to explore existing import safety-related agreements with foreign governments and to coordinate future agreements to benefit the United States and not merely individual agencies.

A variety of actions and plans are already underway to improve import safety. Today, the Food and Drug Administration is releasing a new Food Protection Plan. In September, the Consumer Product Safety Commission signed a renewed agreement with the People's Republic of China focused on the safety of toys, fireworks, cigarette lighters and other targeted products. These steps, and other recent actions and current plans, have jump-started our efforts to continually improve the safety of products imported to the United States.

Each recommendation in this Action Plan falls under the organizing principles of prevention, intervention and response and expands upon the building blocks identified in the Strategic Framework. Together, the Strategic Framework and this Action Plan provide a national strategy for continually improving the safety of imported products.

The information collected and analyzed for this Action Plan reaffirms the essential and integrated import-safety roles of the public and private-sector. Our recommendations pertain to all parties involved in the import life cycle, from production in the foreign country through U.S. ports-of-entry to final consumption or use by American

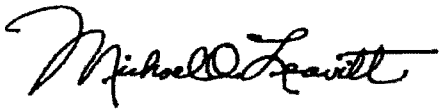
consumers. The public and private-sectors have a shared interest in import safety, and substantive improvement will require the careful collaboration of the entire importing community.

This Action Plan provides a roadmap that ensures the benefits of the global economy and improves the safety of imported products. Progress will require that we work collaboratively, partner with the importing community and state and local governments, and reach out to foreign producers, exporters and governments. By doing so, all involved will be more prosperous and will continue to benefit from an abundant and safe marketplace.

We recommend that Working Group designees meet within 30 days to assess progress in implementation of this Action Plan, and to discuss how best to collaborate with the private-sector to continue effective implementation.

On behalf of the members of the Interagency Working Group on Import Safety, we thank you for the opportunity to serve this great country.

Respectfully,



Michael O. Leavitt
Secretary, Health and Human Services and
Chair, Interagency Working Group on Import Safety

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Introduction

On September 10, 2007, the Interagency Working Group on Import Safety[1] (Working Group) presented an *Action Plan for Import Safety: A roadmap for continual improvement* (Strategic Framework) and Immediate Actions[2] for continual improvement in import safety.[3] The Strategic Framework provides the foundation for this Action Plan for Import Safety. Together, the Strategic Framework, Immediate Actions and this Action Plan fulfill the requirements of Executive Order 13439, which established an Interagency Working Group on Import Safety and was signed by President Bush on July 18, 2007.

A careful examination of import safety has been motivated by the recent challenges presented by an increasingly global economy, in which U.S. consumers are purchasing approximately $2 trillion worth of products that are imported by over 800,000 importers through over 300 ports-of-entry.

In developing the Strategic Framework, Immediate Actions and Action Plan, the Working Group engaged in a campaign to solicit comments and recommendations from the public. Since the release of the Framework, the Working Group has received information and comments from hundreds of stakeholders. Health and Human Services Secretary Leavitt and other Cabinet members traveled throughout the United States and other countries to discuss import-safety issues. They met with federal, state and local officials, producers, importers, distributors and retailers. In addition, they held roundtable discussions and media events to engage the public and importing community[4] in the activities of the Working Group.

The Working Group also met with Members of Congress and representatives of foreign governments to solicit comments and recommendations. The Working Group issued a Federal Register notice requesting written comment and announcing a public meeting, which was held in Washington, D.C., on October 1, 2007. Representatives from the 12 Cabinet departments and agencies comprising the Working Group listened to comments and recommendations from the importing community and the public on import safety. Officials from each member department met with

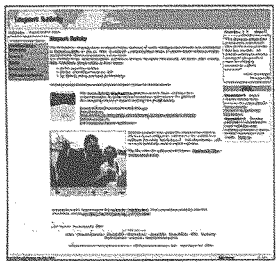
1 The Working Group includes the Secretaries of the Department of Health and Human Services, the Department of State, the Department of the Treasury, the Attorney General, the Secretaries of the Department of Agriculture, the Department of Commerce, the Department of Transportation and the Department of Homeland Security, the Director of the Office of Management and Budget, the United States Trade Representative; the Administrator of the Environmental Protection Agency, and the Chairman of the Consumer Product Safety Commission. The Food and Drug Administration, Customs and Border Protection and the Food Safety and Inspection Service were active participants on the Working Group as well.

2 See Appendix B for the September 10, 2007 correspondence to the President that included these Immediate Actions.

3 See *Protecting the American Consumer Every Step of the Way: A strategic framework for import safety.*

4 The term "importing community" is used broadly throughout this document to include all domestic entities in the supply chain.

scores of their private-sector constituencies to discuss import-safety issues. Texas A&M University convened a Conference on Import Safety Science and Technology on October 18, 2007. Additionally, the Working Group created an import-safety Web site, and utilized novel approaches such as webinars to provide information and to solicit comments and views from the importing community and the public.



The oral comments from the public meeting and the written comments submitted, as well as the input received by the member departments from the public, provided significant input that was used in the development of the recommendations in this Action Plan.

The seminal finding of the Framework was that, to adapt to a rapidly growing and changing global economy, the U.S. government must develop new import-safety strategies that expand and emphasize a cost-effective, risk-based approach. Such an approach identifies risks at the points they are most likely to occur, and then targets the response to minimize the likelihood that unsafe products reach U.S. consumers.

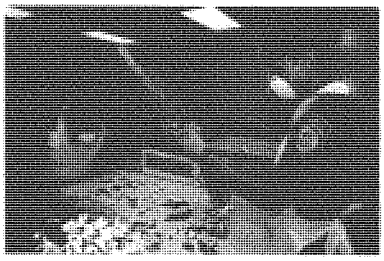
This Action Plan presents broad recommendations and specific short- and long-term action steps under the organizing principles of prevention, intervention and response. Each action item is based on the building blocks identified in the Strategic Framework, released in September 2007. The Strategic Framework and this Action Plan provide a national strategy for continually improving the safety of imported products.

Implementation of this Action Plan will require expanded legal authorities, improved collaboration and capacity building with our trading partners, improved collaboration with state and local governments and the private sector, increased information gathering and the discovery and application of new science. Implementation of the recommendations will require resources, including reallocation of existing resources, as well as trade-offs, to fund these priorities.

The Working Group recommends that representatives of the member departments and agencies meet within 30 days to assess progress in implementation of the Action Plan and to discuss possible mechanisms for collaboration with the private sector to continue the effective implementation of this Action Plan.

Background

This Action Plan builds on the earlier companion report: *Protecting American Consumers Every Step of the Way: A strategic framework for continual improvement in import safety*. That report concluded that the United States must transition from an outdated "snapshot" approach to import safety, in which decisions are made at the border, to a cost-effective, prevention-focused "video" model that identifies and targets critical points in the import life cycle where the risk of the product is greatest, and then verifies the safety of products at those important points.



This Action Plan follows the organizing principles identified in the Strategic Framework – prevention, intervention, and response – and draws on six building blocks:

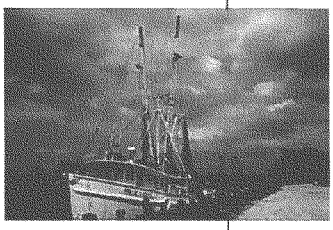
1. Advance a Common Vision;
2. Increase Accountability, Enforcement and Deterrence;
3. Focus on Risks Over the Life Cycle of an Imported Product;
4. Build Interoperable Systems;
5. Foster a Culture of Collaboration; and
6. Promote Technological Innovation and New Science.

Public comments on the Strategic Framework show widespread acceptance and support of the organizing principles and building blocks.

The following is a brief summary of the Strategic Framework that forms the foundation of this Action Plan. Readers familiar with the Framework are encouraged to proceed to the Recommendations section.

Summary of the Strategic Framework

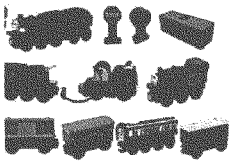
The Strategic Framework advocates a strategy that shifts the primary emphasis for import safety from intervention to a risk-based prevention with verification model. It recommends that the public and private sectors work together to identify risks and consider new approaches for addressing these risks. The vision of the Strategic Framework is to improve continuously the safety of imported products.



Three organizing principles form the keystones of the Strategic Framework and the recommendations included within this Action Plan:

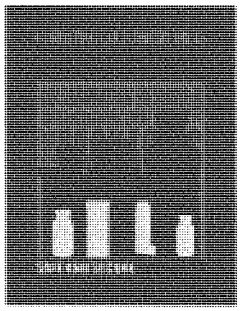
1. **Prevention** – *Prevent harm in the first place.*
   The U.S. government must work with the private sector and foreign governments to adopt an approach to import safety that builds safety into manufacturing and distribution processes. This effort will reduce the risks to consumers from otherwise dangerous imported products.

2. **Intervention** – *Intervene when risks are identified.*
   Federal, state, local and foreign governments, along with foreign producers and the importing community, must adopt more effective techniques for identifying potential product hazards. When problems are discovered, government officials must act swiftly, and in a coordinated manner, to seize, destroy or otherwise prevent dangerous goods from advancing beyond the point-of-entry. For foreign countries, taking steps to ensure the safety of products exported to the United States will benefit them by facilitating trade.



3. **Response** – *Respond rapidly after harm has occurred.*
   In the event that an unsafe import makes its way into domestic commerce, swift actions must be taken to limit potential exposure and harm to the American public.

Within each of these organizing principles are the cross-cutting building blocks identified in the Strategic Framework that departments and agencies should use to guide their programs.



Building Block 1: Advance a Common Vision

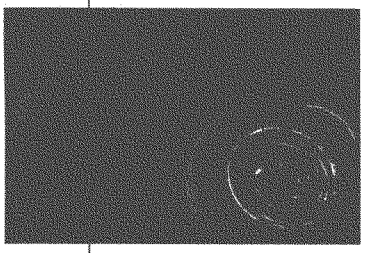
There should be a shared vision and shared goals across the federal government for promoting import safety. Relevant policies and procedures should be reviewed and, where appropriate, revised to ensure that all federal departments and agencies are working together with shared objectives. Revised measures should encourage public and private parties involved in the import life cycle to adopt this common vision.

Building Block 2: Increase Accountability, Enforcement and Deterrence

While it is important to remember that industry has a financial interest to sell safe products to its consumers, all actors involved in the production, distribution and sale of imports must be held accountable for meeting their obligations to ensure that imported products meet safety standards[5] in the United States. The federal government will continue to work with industry to foster compliance with these standards, but is also prepared to use appropriate criminal and civil enforcement tools to hold companies and individuals accountable and to protect consumers.

Building Block 3: Focus on Risks Over the Life Cycle of an Imported Product

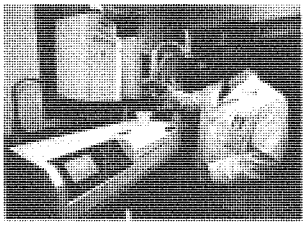
In addition to identifying unsafe products at the border, the new approach must focus on the most important safety considerations affecting imported goods throughout their import life cycle – from overseas production to U.S. ports-of-entry, through final consumption or use in the United States. A key element is developing the ability to identify and manage risk at critical points along the import life cycle. Rather than the primary line of defense, intervention at the border must become one part of a network of interconnected measures that protect the American public and facilitate the entry of safe imports that comply with U.S. statutes and regulations.



The federal government should move to a more risk-based, cost-effective approach to identify and mitigate risks posed by imported products. Principles of hazard analysis and risk management have long been applied in manufacturing as a method of minimizing risks and maximizing quality in production processes. These principles enable the targeting of resources to areas of greatest risk.

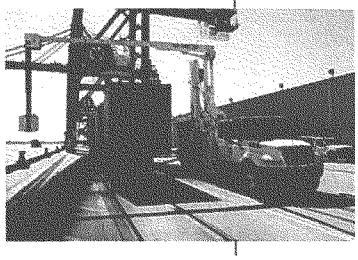
5 "Safety standards" may have a different meaning in different contexts. In this case, we are using the term in a broad sense to refer to recognized standards in the United States that ensure products, including chemical substances and pesticides, are safe for people and animals. By "recognized standards" we are referring to those standards for which compliance is required by United States law or regulation, or for which compliance is voluntary but, if met, is considered by the federal agency with jurisdiction as sufficient to meet federal requirements. These standards can be national or international.

Building Block 4: Build Interoperable Systems
The federal government needs to finalize implementation of interoperable data systems already under development that facilitate the exchange of relevant product information among parties within the import supply chain to ensure import safety. The International Trade Data System (ITDS) initiative is a key component to improve system interoperability. The ITDS initiative will create a single-window environment for the collection of information and will improve and enhance information sharing among government departments and agencies and the import community.



Building Block 5: Foster a Culture of Collaboration
The federal government must develop a culture of collaboration that will permeate relationships among federal departments and agencies and their external stakeholders. All parties (federal, state, and local governments, foreign governments, foreign producers, foreign exporters and the importing community) involved in the import life cycle need to work together to prevent unsafe products from entering the United States and to take swift and effective action if such products do enter domestic commerce. This collaboration must build on international multilateral and bilateral agreements to ensure the safety of products imported into the United States without creating unjustified trade barriers. As some unsafe products result from violations of patents and trademarks, the federal government will also work to increase coordination with U.S. industry to enforce intellectual property rights (IPR) and prevent the entry of counterfeit and potentially unsafe products into supply and distribution chains. This will require a new era of collaboration, as the federal government works to identify better ways to engage all parties in the import life cycle.

Building Block 6: Promote Technological Innovation and New Science
A more effective and efficient import-safety system will depend on the development and application of new science and technology. Implementation of innovative technologies will afford the opportunity to screen larger volumes of imported products at points-of-entry. These screening procedures will help evaluate and target high-risk commodities, increasing analytical efficiency and the number of imported products tested. Research into the causes of risk, such as the conditions that lead to contamination of foods with certain pathogens, can help government and industry identify vulnerable points in the import life cycle for specific products.



These building blocks and the organizing principles provide the foundation for the recommendations that follow.


Import Safety Strategic Framework
Vision
Our aspiration
Continuously improve the safety of imported products
Strategy
How we achieve our vision
Shift focus from intervention to prevention
(over the entire import life cycle)
Organizing principles
How we organize our strategy
Prevention
Intervention
Building Blocks
Steps necessary to achieve our vision
Advance a Common Vision
Focus on Risks Over the Import Life Cycle
Increase Accountability, Enforcement, & Deterrence
Build Interoperable Systems
Foster a Culture of Collaboration
Promote Technological Innovation & New Science

Sample Summary of Actions and Current Plans to Protect American Consumers

As directed by the President, all departments and agencies have been reviewing and assessing current procedures, authorities, outreach efforts and international cooperation initiatives to enhance the safety of imported products. Based on these reviews and meetings, the departments and agencies have already taken numerous actions to protect American consumers. Many more initiatives to enhance the safety of imported products are underway and will be completed in the coming months. Here is a sample of significant recent accomplishments and important actions that will be completed within the first 200 days of issuing this Action Plan. A more complete list is shown in Appendix C: Recent Actions and Current Plans to Protect American Consumers.

Safety Standards

- **Food Protection Plan.** The Food and Drug Administration (FDA) has developed a Food Protection Plan that addresses both food safety and food defense for domestic and imported products, including food protection from production to consumption. The Plan will be phased in over the coming months and is integrated with the Administration's Import Safety Strategic Framework and Action Plan.

Certification

- **Seafood Inspection Program.** As of October 24, 2007, the Department of Commerce's National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program has inspected and certified seven seafood processing plants in China and has plans to inspect another 12 plants. A number of other plants are scheduled to be inspected.
- **Seafood Inspectors Stationed in Other Asian Countries.** NOAA is in the process of stationing an inspector full time in Hong Kong, and has plans to put inspectors in other countries that export large volumes of seafood to the United States.

Foreign Cooperation and Capacity Building

- **Safety Agreement with China on Toys, Fireworks, Electrical Products.** Meetings held in September 2007 between the Consumer Products Safety Commission (CPSC) and its counterpart, the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) of the People's Republic of China, resulted in a renewed Memorandum of Understanding (MOU) related to the promotion of safety for target products – children's toys, fireworks, cigarette lighters, and electrical products.
- **Security and Prosperity Partnership (SPP) priority on Safe Food and Products.** In August, President Bush, President Calderon of Mexico and Prime Minister Harper of Canada pledged to strengthen trilateral cooperation and mechanisms within the region, build on current standards and practices and work with our trading partners outside of North America to identify and stop unsafe food and products before they enter our countries.
- **Memoranda of Agreements with China on Food, Drugs, Medical Devices and Animal Feed.** HHS/FDA is negotiating binding agreements with the Chinese government to enhance regulatory cooperation in the area of drugs, medical devices, food, and animal feed. These agreements will protect the safety and health of consumers and animals in the United States and in China.
- **Motor Vehicle Safety Agreement with China.** On September 12, the Department of Transportation's National Highway Traffic Safety Administration (NHTSA) signed a Memorandum of Cooperation with China aimed at increasing cooperation in the areas of motor vehicle regulation and safety. Both sides indicated a willingness to work together to address issues related to the safety of Chinese motor vehicles and equipment (including tires and automotive fuses) intended for export to the United States.
- **Foreign Training on United States Safety Standards for Meat, Poultry and Eggs.** In July 2007, the United States Department of Agriculture (USDA) and FDA conducted a seven-week training program for Chinese inspection officials. The Food Safety and Inspection Service (FSIS) also conducted outreach to foreign government inspection officials regarding FSIS import requirements for meat, poultry and egg products. FSIS provided technical assistance to the Austrian government regarding U.S. import requirements for ready-to-eat products, to Mexico regarding microbiological testing procedures and to the governments of Bosnia-Herzegovina, Namibia and Thailand about U.S. import requirements in general.

Response

- **Marking Rule to Prevent Port-Shopping.** By mid-2008, FDA will issue a proposed rule that would require imported food that has been refused entry to be marked "United States: Refused Entry." Such marking would help prevent the introduction of unsafe food into the United States through port-shopping, a practice whereby importers attempt to gain entry through a port after the goods have been refused at another.

Recommendations

The current import-safety system in the United States has served the public well for many years and is among the most effective in the world. In this system, the public and private sectors work collaboratively to collect and evaluate pertinent information for all commercial cargo before it reaches the United States. Under U.S. law, cargo that does not meet federal government requirements, including those relating to safety, is not allowed to enter domestic commerce. In a similar fashion, cargo that does not meet the expectations, contractual requirements or safety standards of the private sector jeopardizes trading relationships and compromises business. These legal requirements and market-based measures work together to protect the American public.

> We live in a world that is risky. We will not be able to eliminate all risks, but we also need to manage those risks in a way that is smart and efficient.
>
> Dr. Jeff Runge, Acting Assistant Secretary for Health Affairs, Department of Homeland Security

The recommendations included in this Action Plan build upon the current import-safety system and activities already being undertaken by the public and private sectors by focusing on cost-effective, risk-based approaches across the entire import life cycle. The Working Group presents 14 broad recommendations and 50 action steps, each with a lead entity and time frame. The recommendations include short- and long-term action steps that should commence immediately.[6]

The recommendations are categorized in this Action Plan based on the organizing principles outlined in the Strategic Framework – prevention, intervention and response. Together, the organizing principles, recommendations and action steps create an import-safety roadmap to promote continual improvements in import safety.

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6 "Short term" refers to those action steps that can be completed within the next 12 months; "Long term" refers to those action steps that will take longer to complete.

Import Safety Roadmap

Organizing Principles

Recommendations

1. Create new and strengthen existing safety standards
2. Verify compliance of foreign producers with U.S. safety standards and U.S. security standards through certification
3. Promote Good Importer Practices
4. Strengthen penalties and take strong enforcement actions to ensure accountability
5. Make product safety an important principle of our diplomatic relationships with foreign countries and increase the profile of relevant foreign assistance activities
6. Harmonize federal government procedures and requirements for processing import shipments
7. Complete single-window interface for the intra-agency, interagency, and private sector exchange of import data
8. Create interactive import-safety information network
9. Expand laboratory capacity and develop rapid testing methods for swift identification of hazards
10. Strengthen protection of intellectual property rights (IPR) to enhance consumer safety
11. Maximize the effectiveness of product recalls
12. Maximize federal-state collaboration
13. Expedite consumer notification of product recalls
14. Expand use of electronic track-and-trace technologies

Sample Action Steps

- Establish 3rd party certification
- Make available information about certified firms and importers who only use certified firms
- Increase the dollar amount of bonds
- Expand asset-forfeiture remedies
- Raise the Consumer Product Safety Act (CPSA) statutory civil penalty cap
- Develop capability to exchange information electronically among the federal departments and agencies and with the importing community
- Establish field presence at key foreign ports
- Enhance field laboratory capacity
- Develop best practices for track-and-trace technologies

Footnote: The roadmap includes 50 short- and long-term actions steps. The steps here are a subset of the larger total and illustrative of the recommended actions.

Points of Clarification

Before presenting the recommendations and action steps, several clarifications are helpful:

- **Shared Interest** – The information collected and analyzed for this Action Plan reaffirms the key and integrated import-safety roles of public- and private-sector actors. Both have a shared interest in the safety of imported products and both must continue working together to protect the American consumer. The import-safety chain stretches from the point of foreign origin, both of materials and finished product, to domestic consumption or use. All entities involved in the import life cycle – foreign producers (growers and manufacturers), governments, distributors, exporters, U.S. importers, distributors, manufacturers and retailers, testing and certification bodies and regulatory authorities at the federal, state and local levels – must work together to prevent unsafe products from entering the United States. The appropriate entities in the supply chain must also take swift and effective action when harmful products do enter domestic commerce.

> We believe that the responsibility for safety has to be firmly attached to each link in the supply chain.
>
> Donald Mayes, Consumers Union

- **Private-sector interest and mechanisms** – The private sector not only has a significant interest in ensuring safety, but also has a wide array of mechanisms to support federal objectives. Likewise, the federal government can learn and benefit from the experience of the private sector. Although the action steps in this Action Plan pertain primarily to the federal government, the Action Plan recognizes the importance of private-sector mechanisms and experience and lays a foundation for ongoing, substantive public-private collaboration.

> It makes sense to focus our limited resources on those shipments that pose the greatest risk.
>
> Josh Green, Panjiva

- **Consumer Interest** – The Action Plan recognizes that consumers have a vital interest in the safety of imported products and anticipates active consumer engagement in the implementation of the recommendations and action steps.

- **Risk-based strategies** – This Action Plan is built on the concept that focusing on risk is the most effective way to address safety over the broad spectrum of products imported by the United States. Some areas and products need more attention than others because of the potential risks they could present and because of differences in the product and the production environment. These differences include process controls, the history of compliance, the intended use of the product, the inherent risks of the product and other factors demonstrated by science and experience to be valid predictors of

risk to the public. The federal government must continue to make choices about where it focuses its resources, and basing those choices on risk means that better and more logical decisions will be made with more effective results. Therefore, there is no one-size-fits-all solution. The recommendations and action steps in this Action Plan reflect this cost-effective, risk-based approach.

- **Accountability** – The Strategic Framework stresses that import safety can be advanced through shared efforts and shared responsibility throughout the entire import life cycle, from foreign governments, producers, distributors and exporters to U.S. importers, producers, distributors and retailers, as well as the federal and state governments. Any private entity that seeks to benefit from access to the U.S. market has the same responsibility domestic producers have to ensure their products meet all applicable U.S. safety standards. For example, producers of drugs and medical devices are expected to meet the standards set by the FDA. Steps to create incentives for foreign firms to ensure this outcome are an important part of the Action Plan. In addition, the U.S. importing community, either as a link in the U.S. distribution chain or as the seller to the ultimate consumer, must share the commitment to ensure that products brought into the United States are manufactured in accordance with U.S. safety standards.

  All entities involved in the import life cycle are responsible for ensuring the safety of the products they produce, distribute, export, import or sell. The specific responsibilities of each entity depend on the activities in which they engage. For example, producers are responsible for making products that comply with U.S. safety standards. Importers are responsible for bringing products that meet U.S. safety standards into this country in a manner that does not compromise the safety and, where appropriate, efficacy of the product.

Facilitate Trade but Target High-Risk Imports
The recommendations in this Action Plan are designed to promote import safety while avoiding restrictions on the flow of international trade. Some recommendations provide incentives to foreign producers, suppliers, and importers that will expedite the entry of products that meet U.S. standards. Others lead to greater information about these entities. These incentives and the collection of better information will enhance the capacity of the federal government to focus on those products that may present a risk to consumers in the United States. By improving the management of risk, we can facilitate the trade of safe products and devote more personnel and resources to high-risk products and products of unknown risk.

- **Resources** – To implement the Action Plan to its fullest extent will require resources. Federal departments and agencies will coordinate, plan effectively and meet these goals by submitting additional funding needs through the normal budget process.

- **Common mission, varying statutory roles** – While the entire federal government is responsible for advancing import safety, each department and agency operates within a unique statutory framework. The recommended actions do not apply uniformly to all federal entities. Instead

they are tailored to product risk and the relevant statutory frameworks serve as tools to improve the safety of imported products on an ongoing basis. Where appropriate, the action steps identify affected departments and agencies.

- **Complementary Findings** – The recommendations and action steps outlined in this Action Plan take into consideration the wide array of other planned or ongoing actions by the federal government and other entities to improve the safety of imported products. The findings of this Action Plan are additive and complement other meaningful changes and programs. Appendix C includes a summary description of recent activities and current plans that expand upon and complement this Action Plan.

> The United States import safety system must be a comprehensive, risk-based, preventative approach in which food manufacturers build food safety into their products. Indeed, the changing import environment for our increasingly global food supply demands a new approach to import safety.
>
> John D. Floros, Ph.D.
> Institute of Food Technologists

Implementation

Effective implementation will require the concerted effort of all participants in the import life cycle, creating an expanded culture of collaboration. The federal government must lead by example to build each of these recommendations into agency priorities and budgets. To aid in this process and ensure accountability, each action step has a designated lead agency or agencies.

Prevention with Verification

This Action Plan recommends using market-based and regulatory incentives and deterrents to encourage foreign entities to build safety into products destined for the American market and to encourage domestic entities to ensure that the products they import meet safety standards in the United States. This approach holds all participants in the import life cycle, both foreign and domestic, accountable for ensuring the safety of imported products by using a cost-effective, risk-based strategy. It includes:

- Creation of mandatory and voluntary third-party certification programs for foreign producers that are based on product risk to verify compliance with U.S. safety standards,
- Development of good importer practices, and
- Use of strong penalties against bad actors.

Based on their risk, many products may not warrant the establishment of a mandatory or voluntary certification program. The federal government will also work with its trading partners to promote, where needed, the development of the regulatory capacity and legal systems necessary to ensure the safety of the products they export to the United States.

Safety and Security
Since the United States government bases its decisions about whether or not a product may enter the country on both safety and security considerations, certification programs referenced in the action steps would assess compliance with both safety and security standards. In today's world, certification for import safety and certification for import security need to be closely coordinated. Consideration should be given to merging these two certification processes into one program.

The following recommendations, action steps, lead entities and time frames present a detailed roadmap for further action.

Safety Standards

Recommendation 1 – Create New and Strengthen Existing Safety Standards

An organizing principle of the Strategic Framework is the concept of prevention with verification. This concept is predicated on a philosophy of building assurances of safety into production processes and establishing appropriate supply-chain controls, rather than relying solely on physical inspection and testing of products at ports-of-entry to identify and mitigate safety hazards. Prevention with verification embraces the incorporation of science-based safety standards into production and distribution systems, combined with compliance assessments to ensure these standards are being met.

Industry best practices have long reflected a commitment to the use of risk-based preventive controls as an effective mechanism for assuring product safety. The federal departments and agencies with jurisdiction over imported products should work with industry, standards development organizations and other members of the public to strengthen U.S. safety standards, where needed and appropriate, particularly for products determined to be high-risk. Federal departments and agencies should also increase their participation in international standards-setting organizations to encourage the development of international standards that reflect, to the extent possible, the same level

of protection maintained in the United States. When adopting or developing safety standards, the federal department or agency with jurisdiction should consider the best available science, industry best practices and standards set by credible national and international standards development organizations.

1.1 *Extend the mandatory manufacturer/importer certification requirement under section 14 of the Consumer Product Safety Act to all statutes administered by Consumer Product Safety Commission.* All mandatory safety standards promulgated by the CPSC under the CPSA require a manufacturer's or importer's certification of conformity to those standards. The other key statutes administered by the CPSC do not contain similar certification provisions for mandatory safety standards. In the CPSC's experience, requiring the certification of conformity improves supplier compliance with mandatory standards. The requirement simplifies and strengthens enforcement at ports because products that are not accompanied by a declaration of conformity must be refused entry. Also, because it is unlawful to issue a false declaration, firms can not easily circumvent the requirement. As a benefit to inspecting officials, the process of checking for a certificate is not burdensome and does not require any additional government testing or evaluation. Extending the existing conformity requirement under the CPSA to other statutes administered by the CPSC would enhance the Commission's ability to ensure product safety.
Lead: CPSC
Time Frame: Short Term

Apply the Same Safety Standards to Domestic and Foreign Made Products
A product sold to American consumers should be safe regardless of whether it is made in the United States or abroad. These recommendations are aimed at ensuring that foreign producers, exporters and distributors, as well as importers, are held accountable for compliance with the same product safety standards as producers and distributors in the United States. Consistent with international trade rules and longstanding United States practice, any new safety rules will be transparent, will be based on available scientific and technical information and will not discriminate unfairly against imported products over domestic products.

1.2 *Clarify the Food and Drug Administration's (FDA) authority to require preventive controls for certain foods.* This action step would strengthen FDA's ability to require, by regulation, preventive control measures to address risks that might occur for domestic and foreign produced foods associated with repeated serious adverse health consequences or death from unintentional contamination. FDA would take into consideration industry best practices, such as Hazard Analysis and Critical Control Points (HACCP) requirements.
Lead: HHS / FDA
Time Frame: Short Term

1.3 *Provide the FDA with authority to require measures to prevent the intentional contamination of domestic and foreign foods.* The FDA would use this authority to issue regulations to require companies to implement practical food defense measures at specific points in the food supply chain where the potential for intentional adulteration resulting in serious adverse health consequences or death to humans or animals is the greatest. This authority would apply to food in bulk or batch form, prior to being packaged.
Lead: HHS / FDA
Time Frame: Short Term

1.4 *Examine food-safety control systems of other countries to determine whether improvements can be made to the operation of FDA's food regulatory program.* The examination would provide FDA with comprehensive knowledge of food safety systems of other countries. FDA could identify elements or components of those systems that are recognized as food safety system "best practices" and utilize them to strengthen and enhance FDA's prevention, intervention and response activities.
Lead: HHS / FDA
Time Frame: Long Term

1.5 *Expand the use of public-private sector standards programs.* Standards programs established and administered by the private sector with input from government can provide a generally accepted forum for developing safety standards. Organizations such as the International Organization for Standardization and U.S.-based international standards developers accredited by the American National Standards Institute devise standards that the federal government may subsequently recognize. Greater use of these venues can accelerate the development of needed safety standards. They should be pursued, as appropriate, as long as the standards developed are based on sound scientific information and utilized domestically.
Lead: Department of Commerce
Time Frame: Long Term

Certification

Recommendation 2 – Verify Compliance of Foreign Producers with United States Safety and Security Standards Through Certification

Import certification can augment federal department and agency resources, facilitate trade by expediting the entry of products from certified firms, and assist the importing community in implementing effective Good Importer Practices. As appropriate, certification would include periodic on-site inspections and random testing. Certification would need to be renewed periodically at intervals that could vary based on product risk, such as with greater frequency for high-risk goods. This Action Plan contemplates the use of both mandatory and voluntary certification.

The federal departments and agencies with jurisdiction over imported products should work with regulated industry and other members of the public to strengthen U.S. safety standards, where needed and appropriate, particularly for products determined to be high-risk.

The Action Plan recommends tailoring import certifications to both the product's level of risk and its intended use. Currently, federal departments and agencies use import certifications in a variety of contexts. For example, as a condition for export of meat, poultry and egg products to the United States, the Food Safety and Inspection Service (FSIS) certifies foreign countries that, in turn, certify producers that meet U.S. requirements. Such certification ensures that the products comply with U.S. requirements. While requiring import certifications for all goods is not necessary, in certain circumstances (e.g., high-risk products), this extra step may be warranted. Therefore, the Action Plan recommends mandatory certification for select high-risk products.

The Action Plan also recommends expanded use of voluntary import certifications for other products. To encourage and assist foreign producers to meet U.S. standards, the federal government should establish voluntary certification programs as appropriate. Voluntary certification programs may provide importers with important compliance information and help them ensure that the products they import meet U.S. standards. If widely used, these programs will also assist the federal government in properly targeting inspection resources to those products of greatest risk. For this reason, we propose incentives to motivate voluntary participation. For example, products made by certified firms would generally receive expedited processing at U.S. ports-of-entry. Furthermore, the federal government will ensure that information about certified firms and importers of record is easily accessible to the public.

> Manufacturers will demonstrate compliance with national standards when there is value in it for them, such as recognition at the border by customs, preference by distributors and retailers, and selection by consumers.
>
> Stan Hazan, NSF International

Mandatory Certification

Mandatory certification may be necessary to ensure that imported products are safe in certain circumstances. This would involve safety considerations, including risks associated with the product itself or its place of origin. Generally, in such cases, the only other option available is to deny the entry of these products into the United States. In requiring that such products be certified, or produced by a certified firm in order to be imported, a mechanism would be provided that allows trade to continue flowing while also enhancing safety.

2.1 *Provide the FDA with the authority to require a certification or other assurance that a product under its jurisdiction complies with FDA requirements.* Certification would be mandated based on risk and generally would apply to products coming from a particular country, region, or producer where safety cannot be adequately ensured for these products in the absence of such assurance. This would allow the FDA to redirect its resources to other products. Such import certification programs would be used for designated products imported from countries with which FDA has an agreement to establish a certification program that provides sufficient safety to meet HHS/ FDA standards. FDA would accept certifications from either relevant government agencies or accredited third parties.
Lead: HHS/FDA
Time Frame: Short Term

Voluntary Certification

For foreign producers, the ability to participate in voluntary certification programs could allow products from firms that comply with U.S. safety and security standards to enter the United States more quickly. This would facilitate trade, while allowing federal departments and agencies to focus their resources on products from non-certified firms or for which information suggests there may be safety or security concerns. This would allow federal

departments and agencies to more effectively target their resources. It may not be necessary to establish certification programs for low-risk products.

2.2 *Develop voluntary certification programs based on risk for foreign producers of certain products who export to the United States.* The federal government will work with the importing community and other members of the public to develop voluntary certification programs, as appropriate, based on risk. As part of this effort, the federal government should take into consideration, incorporate or expand upon existing trusted trader partnership programs including CBP's Importer Self Assessment Program (ISA) and programs that relate to security.[7]
Leads: CPSC, HHS / FDA, DHS / CBP
Time Frame: Long Term

In September 2007, the U.S. Toy Industry of America (TIA) announced plans to implement new compliance systems to bolster the safety of toys sold in the United States. The initiative, created in consultation with the American National Standards Institute and the Consumer Product Safety Commission, includes the development of standardized testing procedures and laboratory certification criteria.

2.3 *Provide FDA with legislative authority to accredit independent third parties to evaluate compliance with FDA requirements.* To implement the previous action step (2.2), FDA will accredit third party organizations, or recognize an entity that accredits third parties. Third party organizations could be, as appropriate, federal departments and agencies, state and local government agencies, foreign government agencies, or private entities without financial conflicts of interest. FDA would use information from these accredited third party organizations in its admissibility decision-making.
Leads: HHS / FDA
Time Frame: Short Term

2.4 *Create incentives for foreign firms to participate in voluntary certification programs and for importers to purchase only from certified firms.* The federal government should establish these incentives, which could include expedited entry, expedited processing of samples for laboratory testing, and access to CBP's account manager program. Utilizing expedited entry, federal departments and agencies with jurisdiction typically would be much less likely to physically examine or otherwise delay products made by certified firms unless the product is examined for auditing purposes, there is information suggesting this product violated U.S. law, is considered high-risk for safety or security reasons, or the importer of record did not provide correct or complete information

The United States is unique to the world in many ways, including the fact that it relies heavily on the private sector for voluntary standards development, as well as product safety testing and certification services.

August W. Schaefer
Underwriters Laboratories Inc.

7 ISA is a voluntary program for importers who agree to monitor their own compliance in exchange for benefits from CBP. Its primary objective is to maintain a high level of compliance with United States entry requirements through a cooperative partnership and information exchange between the importing community and CBP.

required by U.S. law. Should samples be taken for testing from a product made by a certified firm, the agency with jurisdiction could expedite processing of those samples. Under CBP's account manager program, the importer of record is assigned a contact person who can answer questions and facilitate the resolution of problems should they arise. The federal government will also consider setting less stringent bonding requirements as an incentive to import products from certified firms.

Leads: DHS / CBP, HHS / FDA, CPSC
Time Frame: Long Term

There are many private sector and government organizations that presently certify products and producers es meeting established national or international standards or accredit certifying bodies. The presence of such certifying or accrediting organizations serves as a ready resource to implement new voluntary certification programs.

2.5 Develop a plan to ensure that information regarding certified firms and importers of record is easily accessible. This will help importers to more easily determine whether or not a foreign firm is certified, and help distributors and retailers to identify importers of record who only handle goods from certified firms. It will also help insurers use this information for determining risk when underwriting importers of record, and help consumers determine whether or not a foreign-made product sold under its own label comes from a certified firm.

Leads: DHS / CBP, HHS / FDA
Time Frame: Long Term

Good Importer Practices

Recommendation 3 – Promote Good Importer Practices.

We owe it not only to our consumers, but, of course, our farmers, ranchers and producers as well. And we must work with our trading partners to share best practices and agree on common standards of science-based approaches for food safety.

Chuck Conner
Acting Secretary of Agriculture

Although some members of the importing community have established and met their own best practices, the importing community does not have available Good Importer Practices focused on ensuring product safety throughout the supply chain. Developing such practices can assist the entire importing community in taking appropriate steps to ensure the safety of the products they bring into the United States.

To encourage the importing community to take appropriate steps to ensure the products they bring into this country meet U.S. standards, the federal government will work with the importing community to develop Good Importer Practices. These practices should be developed as guidelines, be risk-based and provide concrete guidance to the importing community for evaluating imported products. This evaluation would be based on due diligence and preventive controls principles. These practices will provide a set of factors that can be used by the importing community to evaluate foreign suppliers and products.

Based on this evaluation, the importing community will have greater confidence that the products they import will be in compliance with U.S. laws and regulations. For example, for products with known risks, a key precaution

the importing community could take to ensure safety consistent with Good Importer Practices is to purchase, distribute and sell products made by certified producers. As part of this collaboration, the federal government and the importing community should consider whether and how to foster the development of voluntary third-party programs to certify importers as meeting Good Importer Practices.

3.1 *Develop Good Importer Practices.* The federal government should work with the importing community and other members of the public to develop Good Importer Practices and issue guidance with respect to particular product categories. The focus of these practices will be to ensure that imported products meet U.S. safety standards, as well as to promote effective supply-chain management. Development of these practices would help the importing community take appropriate steps to ensure the safety of the products they bring into the United States.
Leads: USDA, CPSC, HHS / FDA, DHS / CBP, Department of Commerce (DOC)
Time Frame: Long Term

3.2 *Partner with the importing community to foster the creation of voluntary certification programs for importers.* These programs would be private-sector based and would serve to verify compliance with Good Importer Practices. The federal government would evaluate these programs to determine whether they should be accredited by the federal government and whether certification should be required for importing certain high-risk products.
Leads: CPSC, HHS / FDA, DHS / CBP, DOC
Time Frame: Long Term

Penalties

Recommendation 4 – Strengthen Penalties and Take Strong Enforcement Actions to Ensure Accountability.

To hold both foreign and domestic entities accountable and discourage them from producing, distributing, exporting, importing and selling unsafe products, the federal government will take steps to strengthen penalties against entities that violate U.S. laws. Effective penalties can serve as a deterrent against violating U.S. requirements and will improve compliance with U.S. safety standards and laws.

Rigorous enforcement of U.S. import-safety laws promotes deterrence. Assessing civil and criminal penalties against bad actors creates the proper incentives for all parties across the import life cycle to behave lawfully and responsibly and to build safety into their products to prevent harm to consumers. For enforcement to be an effective tool in the promotion of import safety, however, civil penalties must amount to more than a business expense

and, for the worst offenders, criminal penalties should apply. Where penalties are weak or lacking, enforcement measures must be strengthened to reflect a meaningful expectation of accountability.

Bonds serve as a guarantee of payment for specific types of penalties levied against the importer. Minimum bond amounts have not changed since 1991 and do not reflect the likelihood that a product may not meet U.S. importing or safety requirements. Compliance with U.S. safety requirements can be encouraged by raising the minimum bond amounts and increasing CBP's authority to consider the risk presented by a product in calculating bond amounts.

> As the volume of imported food steadily increases, the FDA's job at the border can be compared to trying to find a needle in a haystack. We need to approach this task ... by reducing the number of needles to find, and by reducing the size of the haystack in which to find them.
>
> Scott Faber,
> Grocery Manufacturers Association/
> Food Products Association

4.1 Amend the Federal Food, Drug, and Cosmetics Act (FDCA), the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA) and the Consumer Product Safety Act (CPSA) to include asset-forfeiture remedies for criminal offenses. This proposal would allow the forfeiture of all vessels, vehicles, aircraft and other equipment used by bad actors to aid in the importing, exporting, transporting, selling, receiving, acquiring or purchasing of products in violation of the FDCA, FMIA, PPIA, EPIA or CPSA, as well as the proceeds from the criminal offense. Such penalties would apply only to those actors who knowingly and willfully violate the act, and the court of record would make the ultimate determination of relief. This action would be wholly administered by the Department of Justice (DOJ) consistent with current practice under many statutes.[8]
Lead: DOJ
Time Frame: Short Term

4.2 Raise the statutory civil penalty cap under the CPSA. Currently, the penalty cap stands at $1.8 million for any related series of violations under the CPSA. Raising this amount to $10 million would serve as a deterrent to unlawful conduct and provide the CPSC with leverage to negotiate penalties against violators. In assessing penalties, the CPSC should consider whether a company is a repeat offender.
Lead: CPSC
Time Frame: Short Term

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8 For example, Congress limited all criminal forfeiture and the civil forfeiture of real property for drug offenses to felony violations of the Controlled Substances Act (see 21 U.S.C 853 (a) and 881 (a) (7)). So, too, could Congress limit forfeiture sanctions to the statutory provisions that require a knowing and willful violation.

4.3 *Strengthen CBP's mitigation guidelines and increase the maximum penalties against importers who repeatedly import products that violate U.S. law.* CBP needs to impose maximum penalties against such parties to provide effective deterrence.
Lead: DHS / CBP
Time Frame: Short Term

4.4 *Increase the dollar amount of bonds that importers of record must provide to reflect inflationary increases and risk.* Without an adequate bond, CBP is unable to issue and collect penalties for bad actors in the amount allowable by law.
Lead: DHS / CBP
Time Frame: Short Term

4.5 *Authorize FDA to refuse admission of imported products if access--including access to all applicable records, equipment, finished and unfinished materials, containers and labeling--to any factory, warehouse or establishment in which a product for export to the United States is manufactured, processed, packed or held is unduly delayed, limited or denied.* An important tool for the federal government to verify whether a firm complies with U.S. safety standards is to conduct a routine inspection and to review relevant production and distribution records. Domestic firms have an incentive to work with federal departments and agencies with such inspection authority because efforts to delay, limit or deny such an inspection may lead to an enforcement action. However, foreign firms can often deny U.S. officials access to their facilities without any adverse consequence. Having the authority to prevent entry of products from firms that fail to provide FDA access will enable FDA to protect consumers by keeping potentially unsafe products from entering U.S. markets. This authority also will provide a strong incentive for foreign firms to allow FDA to perform inspections, motivation similar to that provided to domestic firms.
Lead: HHS / FDA
Time Frame: Short Term

> Enforcement plays an important role, not just in remedying past harms, but by providing proper incentives and deterrents, which, in turn, help to prevent harm to consumers in the first place.
>
> John O'Quinn, Deputy Associate Attorney General, Department of Justice

4.6 *Provide authority for the destruction of medical products refused admission into the United States.* The federal government has had limited success in stopping unsafe medical products for personal use from entering the United States because of the statutory requirements that must be met before those products are destroyed. Expedited destruction of these products would address this limitation but would only apply to refused shipments that are valued below a certain threshold or which pose a certain level of risk to humans or animals. This is intended to address problems, such as personal shipments of drugs being re-imported after they have been denied entry.
Lead: HHS / FDA
Time Frame: Short Term

4.7 *Remove the notice requirement for violations of the CPSA.* Under its enabling statute, the CPSC must first provide the offending party with notice of its violation prior to prosecution by the DOJ. Although the notice requirement is designed to ensure that a violating firm was aware of its offense prior to prosecution, the standards for prosecution are such that the DOJ must prove knowledge and intent on the part of the offender. Thus, the notice requirement in the CPSA is unnecessary.
Leads: DOJ, CPSC
Time Frame: Short Term

Foreign Collaboration and Capacity Building

Recommendation 5 – Make Product Safety An Important Principle of our Diplomatic Relationships with Foreign Countries and Increase the Profile of Relevant Foreign Assistance Activities.

In the global economy, import safety begins abroad. While many of our trade partners have active and effective programs, some lack an adequate regulatory regime or legal system, both of which are conducive to maintaining and enforcing adequate product safety standards. U.S. investment in capacity building can benefit developing nations by helping them strengthen their economies, enhance their legal systems and public health infrastructure and ultimately facilitate commerce.

While many federal departments and agencies offer capacity-building support to foreign countries, and many U.S. assistance programs provide training in the rule of law and government oversight of products standards and testing, the United States needs to reinforce the importance of product safety as a priority in our broader diplomatic relationships.

For example, in order to develop foreign regulatory capacity building and accountability, the United States needs to advance import safety when negotiating cooperative arrangements with other countries. Further, the United States needs to build effective coalitions with our trading partners and encourage them to become more involved in identifying solutions to product safety challenges.

In addition to building the regulatory capacity of foreign governments, it is vital that the United States share information with foreign counterparts who have active and effective regulatory programs. There is currently information in the hands of foreign governments — such as foreign inspection results, best practices, adverse event reports and data on recalls and outbreaks — that could be useful to U.S. regulatory agencies to better screen products arriving at the border. For example, FDA has begun an active information-sharing program with many of its foreign counterparts to obtain information about

product approval, inspection, testing and safety for FDA-regulated food, medical products and cosmetics.

5.1 *Direct the federal government to make product safety a guiding principle in negotiating future cooperative arrangements with foreign government entities.* To foster effective relationships with foreign government counterparts and demonstrate the importance of product safety in international trade, the United States should make product safety an important component of cooperative arrangements.
Lead: Executive Office of the President (EOP)
Time Frame: Short Term

> The more data that can be captured early in the supply chain process, the better. If U.S.-based importers, retailers and government agencies can identify product safety problems in the manufacturing or transportation stages before a product reaches the U.S. market, the public will be safer, and enforcement and recall costs will be significantly reduced.
>
> Donald P. Bliss
> National Infrastructure Institute

5.2 *Expand and administratively streamline, as appropriate, government inspections in foreign countries and improve collaborative investigation and enforcement activities when negotiating cooperative arrangements with foreign governments.* Streamlining bureaucratic processes, such as the visa process for government inspectors, can result in more-timely and less-costly authorized foreign inspections. In addition, as appropriate, federal departments and agencies should provide foreign countries with training and technical assistance regarding U.S. standards and conformity assessment practices.
Lead: Department of State
Time Frame: Long Term

5.3 *Review existing overseas programs that target rule of law, regulatory capacity-building and trade capacity-building, to determine how to improve product safety standards and conduct.* This would encourage departments and agencies with relevant programs to include product safety standards and compliance, where appropriate, in their capacity-building efforts. Existing foreign assistance efforts related to strengthening the rule of law, regulatory capacity-building and trade capacity-building may currently seek to improve product safety standards and compliance. However, there has been no coordinated policy review of these efforts to help policy makers understand if the level of effort is appropriate and effective and to ensure consistency in U.S. policy.
Lead: Department of State
Time Frame: Long Term

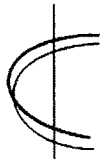
Strengthen the Capacities of Our Trading Partners
One way to ensure compliance with United States safety standards, if warranted, is to increase the capacity of our trading partners to adopt strong safety standards and regulations and to develop a legal system that is capable of enforcing those standards.

5.4 *Improve U.S. liaison to foreign countries.* For example, establish FDA field presence at key foreign ports of embarkation and a CPSC liaison to certain countries.
Leads: HHS / FDA, CPSC
Time Frame: Long Term

5.5 *Develop strategic information-sharing arrangements with key foreign government counterparts.* Through greater information-sharing, such as data on recalls, the federal government can leverage the inspection and regulatory expertise and experience of foreign regulatory authorities to facilitate admissibility determinations, provide advance notice of problems, and enhance enforcement capabilities.
Leads: HHS / FDA, USDA, CPSC, EPA
Time Frame: Long Term

> We're working with foreign governments, informing them of our environmental requirements and helping them to strengthen their capacity to comply with U.S. standards.
>
> Stephen L. Johnson
> Administrator, Environmental Protection Agency

Intervention



The second organizing principle—Intervention—recognizes the need to intervene when risks to product safety are identified. These recommendations address the importance of focusing intervention activities throughout the life cycle of imported products, rather than just at the time the goods arrive at the U.S. border. To accomplish this, the federal government will need to put in place automated systems and foster a culture that optimizes both government and private-sector knowledge. The incompatible systems that comprise the current approach must be replaced with interoperable systems that provide all regulatory departments and agencies, as well as the importing community, with the most complete information possible while protecting confidential information. This will allow federal agencies, either prior to shipment, at the port-of-arrival, or at the port-of-entry, to effectively target shipments that may represent a risk if allowed entry into the United States. This would maximize the use of federal resources and facilitate legitimate trade, as well as assist the importing community in meeting its responsibility to ensure unsafe products do not enter the United States.

Common Mission

Recommendation 6 – Harmonize Federal Government Procedures and Requirements for Processing Import Shipments.

Border officials inspect and clear cargo before it enters the United States in accordance with relevant federal laws and regulations. New risk information can complicate efforts to conduct inspections of entering shipments consistent with the applicable admissibility requirements. Better coordination among federal regulatory departments and agencies; cross-training; commissioning of federal personnel in the application of import entry requirements; and the establishment of common inspection, testing and enforcement protocols are needed, in some cases, to ensure that only products that comply with relevant regulations and standards enter domestic commerce, and that federal efforts to achieve this goal are effective and efficient.

> We're committed at the Food and Drug Administration to continuing to foster the collaboration among other federal agencies and with the states to fully implement the shift to a prevention, intervention and response strategy.
>
> Andrew C. von Eschenbach, M.D.
> Commissioner, Food and Drug Administration

6.1 Develop uniform interdepartmental procedures, where appropriate, for clearing and controlling shipments at ports-of-entry. These procedures would be used by all federal departments and agencies, where appropriate, and would help streamline the entry process as well as facilitate the exchange of information and intelligence, processing of samples and interagency coordination so that federal resources are used more efficiently and effectively in assuring product safety. As part of this action, federal departments and agencies with border regulatory responsibilities

should develop and deliver cross-training, where necessary, to keep the agencies updated on current U.S. import requirements.
Leads: DHS / CBP, USDA, HHS / FDA, CPSC, EPA
Time Frame: Short Term

6.2 *Develop a strategic plan for rapid response to import-safety incidents.* To implement an effective rapid response requires coordination among all the involved parties. This plan would identify the roles and responsibilities of the federal departments and agencies; include a communication plan with state and local governments, private industry, foreign governments, the media and others; and include a business resumption model, as applicable.
Leads: DHS / CBP, USDA, HHS / FDA, CPSC, EPA
Time Frame: Short Term

6.3 *Co-locate border officials from multiple agencies, when feasible, to enhance targeting and risk-management decisions on import safety.* Border officials can work together more effectively when stationed at the same location. The federal government has co-located border officials in limited locations in the past, including CBP's National Targeting Center (NTC),[9] resulting in improved coordination and more effective operations.
Leads: DHS / CBP, HHS / FDA, USDA / FSIS, CPSC
Time Frame: Long Term

6.4 *Exercise commissioning and cross-designation authority to leverage federal resources to prevent unsafe products from reaching consumers in the United States.* Under this model, participating agencies would agree that one agency would act under the authority of the other to carry out select activities, such as audits and lab processing, dependent on capacity constraints. Commissioning is particularly helpful when one agency has staff at a location where the other does not.
Leads: DHS / CBP, HHS / FDA, USDA / FSIS, CPSC
Time Frame: Long Term

Interoperability

Recommendation 7 – Complete a Single-Window Interface for the Intra-agency, Interagency and Private Sector Exchange of Import Data.

In Fiscal Year 2006, 31.3 million entries were filed with CBP for import shipments. Today, interactions between the government and importing community frequently involve time-consuming, resource-intensive paper reporting. The Automated Commercial Environment (ACE), which is currently

9 The NTC is a CBP facility where federal officials are co-located to enable better risk-assessment and targeting of imported cargo.

being developed, will provide an automated "single-window" system for processing the entry of import shipments.[10] Information about imported commodities will be collected for all federal departments and agencies involved in the importing of goods. Through ACE, the importing community, CBP and other federal departments and agencies will exchange real-time data about products, compliance and revenue for each import transaction. The federal government would therefore base a decision to clear or reject an import shipment for entry into the United States upon an immediate information exchange. This would facilitate cargo movements as well as more effective risk determinations and enforcement actions.

The Safety and Accountability for Every (SAFE) Port Act of 2006 makes implementation of the single-window concept a mandatory requirement for federal departments and agencies with import and export responsibilities.[11] Agencies that license, permit, or certify the importation of products into the United States must establish an electronic interface with CBP's ACE system as part of the International Trade Data System (ITDS) initiative. ITDS is developing a Standard Data Set (SDS) of data elements to be used in reporting international trade transactions, which will facilitate exchanging data among all parties involved with an import transaction including regulatory and enforcement agencies.

> The success of the Food Safety and Inspection Service and other agencies has been the result of the extensive import information that's available electronically in both ITDS and ACE on imports and importers ... It is a tremendously powerful tool to give you the information you need in order to be able to assess the risk.
>
> Samuel Banks,
> Sandler & Travis Trade Advisory Services

7.1 Require federal departments and agencies by the end of 2009 to have the capability to exchange commercial data and, to the extent allowable by law, communicate electronically with the importing community and other departments and agencies through ACE / ITDS. ACE / ITDS will permit integration of import data collected by federal departments and agencies to facilitate decision-making on the safety of imports. As part of this action step, departments and agencies, in partnership with the importing community, should develop a coding system for imported products and participants in the import life cycle, as well as draft any regulations necessary for implementation. The coding system will provide greater specificity than currently provided under the Harmonized Tariff Schedule (HTS) and will, thus, help identify products more quickly and accurately. The necessary regulations will be issued by the participating departments and agencies with jurisdiction.
Lead: DHS / CBP and Treasury as executive agents
Time Frame: Long Term

ACE / ITDS Data
In 2006, FSIS gained access to data from CBP's ACE. Since then, detection of illegally-entered meat and poultry products has increased 60-fold. These products have either been destroyed or returned to FSIS for import re-inspection. In all, FSIS has prevented over 3.5 million pounds of illegal meat and poultry products from entering United States commerce.

10 The Immediate Actions Memorandum (September 10, 2007) required that the implementation of ITDS be accelerated. (See Appendix B)
11 The Act permits the Office of Management and Budget (OMB) to exempt certain agencies.

We are finding that the ACE system data are allowing us more efficient collection and analysis of records of incoming consumer products and helping us identify likely shipments of violative products before they can be introduced into the stream of commerce.

Nancy A. Nord
Acting Chairman, U.S. Consumer Product Safety Commission

7.2 Develop, as appropriate, within the Automated Targeting System (ATS), risk-based screening technologies to target high-risk products in a more effective way and facilitate the entry of low-risk products. Such technologies would use information available through ATS to facilitate risk determinations by federal department and agency officials, thereby expediting the entry of safe and secure products and allowing departments and agencies to better target their resources on high-risk products.
Lead: DHS / CBP
Time Frame: Long Term

7.3 Develop an implementation plan for the integration of the Standard Establishment Data Service (SEDS) module into ACE/ ITDS. SEDS would create a centralized service to provide accurate information on the import supply chain. It would provide unique standard identifiers for establishments (to facilitate verification of involvement) and capture a minimal set of establishment violation data from import transactions at the central source.
Leads: DHS / CBP, USDA, HHS / FDA, EPA, Commerce
Time Frame: Long Term

Information Gathering

Recommendation 8 – Create an Interactive Import-Safety Information Network.

Receipt of advance safety and security data regarding the product, the country of export, the manufacturer, the carrier and the importer prior to export of merchandise allows for a preliminary analysis of import-safety. Analysis of the data is critical to making risk-based determinations on actions to be taken by border officials prior to loading shipments in the exporting country and while they are in transit to the United States. In many cases, making these decisions for further review and examination prior to arrival of the shipment can facilitate the clearance of legitimate trade at the time of arrival in the United States.

For example, the Trade Act of 2002 requires carriers to provide limited data elements prior to loading shipments for export to the United States. The Trade Act provisions apply to all modes of transportation. The 2006 SAFE Port Act allows CBP to collect additional information that is reasonable for security purposes prior to the loading of maritime cargo destined for export to the United States.

8.1 Expand upon existing public-private relationships to seek and share the importing community's recommendations and best practices with other federal departments and agencies for import safety and security purposes, and provide training in accessing this information. The importing community has a great deal of information about the product life-cycle that would assist the

federal government in its enforcement and compliance actions. Use of this data could allow federal departments and agencies to make early determinations of import risk based on data already being collected.
Lead: DHS / CBP
Time Frame: Short Term

8.2 *Identify whether additional information is necessary to enhance import safety as allowed for under the SAFE Port Act.* After gaining experience with information gathered under the SAFE Port Act, the federal government, working with the importing community, may conclude that access to additional security information is necessary to make admissibility determinations based on risk.
Lead: DHS / CBP
Time Frame: Long Term

8.3 *Seek legislation that would provide CBP authority to extend reporting requirements for maritime shipments under the SAFE Port Act to all modes of transportation.* This would allow CBP to require both importers and carriers to submit additional information pertaining to cargo before the cargo is brought into the United States. The information would improve the ability of CBP to identify and target high-risk shipments in order to prevent smuggling and ensure cargo safety and security. CBP would exercise this authority through notice and comment rulemaking.
Lead: DHS / CBP
Time Frame: Short Term

8.4 *Develop a private-sector import-safety interactive information exchange process.* The Department of Homeland Security (DHS) would work with the importing community to address a means for the private sector to report critical import-safety information in a timely manner at one virtual location through existing information-sharing systems. DHS would also use this means to share information with the private sector.
Lead: DHS
Time Frame: Short Term

New Science

Recommendation 9 – Expand Laboratory Capacity and Develop Rapid Test Methods for Swift Identification of Hazards.

Advancement in the discovery, development and application of science and technology to detect problems in imported products more rapidly is essential for effective intervention strategies. Through research to develop more and better detection tools and to improve the reliability of existing tools, the federal government and the private sector can detect contaminants and defects more quickly and accurately. These tools could include real-time diagnostic instruments and methodologies that allow for rapid, on-site analysis of a

particular product, especially those that are high-risk. For example, technology that would allow rapid detection of a contaminant could be expanded to cover food types such as produce and dairy products, reducing analysis time from days to minutes and improving the accuracy of test results. New tools would also be developed to identify additional pathogens. Increasing the speed at which federal departments and agencies can detect problems will allow those departments and agencies to take more rapid action, including expediting import entry review decisions and providing critical health information to the public when a problem is identified with a product in commerce.

Laboratory capacity is critical to rapid response to product emergencies. For example, the Food Emergency Response Network (FERN) is a nationwide network made up of more than 130 federal, state and local public health laboratories that support emergency-response activities related to food defense and food safety. FERN also provides training to member laboratories to use new testing methods and provides funding of selected state laboratories through cooperative agreements.

Support from the Scientific Community
During the recent event involving melamine contamination of imported gluten-vegetable protein, the National Center for Food Protection and Defense (NCFPD) provided subject matter expertise and real-time data analysis to assist federal agencies in responding. NCFPD also developed a case study including lessons learned and key unknowns, conducted a rapid assessment of imported food risks, and initiated a joint research project on imported food vulnerabilities and solutions with FDA and FSIS.

Another example is the Electronic Laboratory Exchange Network (eLEXNET). eLEXNET is a seamless, integrated, secure network that allows multiple federal, state and local government agencies engaged in food safety activities to compare, communicate and coordinate findings in laboratory analyses by using information technology tools. The system enables U.S. health officials to assess risks, analyze trends and identify problem products. It provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods and enhances the effectiveness of federal-state collaboration.

Ongoing efforts to enhance import safety will benefit from current and future contributions from the academic community. In addition to the obvious role of educating and training the next generation of professionals and experts, academia is an important resource for innovating new solutions for import safety. For example, subject matter experts from the academic community provided advice, incident monitoring, event assessment and the capturing of lessons learned during several recent food and agriculture sector incidents, such as the contamination of pet food with melamine and the recent foot-and-mouth disease outbreak in the United Kingdom.

> Because freedom from risk cannot be ensured nor can safety be inspected into products, we agree that the private sector has a leading role in strengthening the safety of imports by building safety into food products.
>
> John D. Floros, Ph.D.
> Institute of Food Technologists

Basic research in new technologies, strategies and tools is a natural contribution to import safety from the academic community. Several academic centers are assisting in developing food and agriculture disease and product contamination monitoring tools as well as training tools and programs. The efforts of the academic community in developing new approaches for risk communication and supply chain resiliency can be most effectively tested and further refined via engagement with government. Multiple federal and state agencies, as well as the private sector, already partner with and support research in the academic community.

9.1 *Enhance field laboratory capacity for testing and work collaboratively with the public and private sectors to develop analytical tools for enhanced rapid screening of larger volumes of import samples.* This will allow the federal government to detect risks and take actions to remove problem products from commerce more quickly and effectively.
Leads: DHS / CBP, USDA / FSIS, HHS / FDA, CPSC
Time Frame: Long Term

9.2 *Increase the capacity and capability of FERN laboratories by developing and validating methods to increase the number of chemical, radiological and microbial threat agents that can be rapidly detected in food as well as broadening the reach of the methods to allow foreign laboratories to provide information.* Ensuring adequate capacity and capability of FERN provides a strong surge capacity that is independent of FDA, USDA and EPA laboratory operations.
Lead: HHS / FDA, USDA / FSIS
Time Frame: Long Term

9.3 *Develop rapid test methods for pathogens and other contaminants to ensure that test results are quickly available at ports-of-entry for determining whether or not a product should be admitted into the United States.*
Leads: HHS / FDA, USDA
Time Frame: Long Term

9.4 *Increase the quantity and quality of data submitted by participating laboratories to eLEXNET.* FDA would create an automatic data exchange, which would increase the quantity of samples and/or analytes (the components of laboratory tests) a laboratory is able to submit, increase the frequency and timeliness of data submission and ensure a better degree of data integrity as compared to manual data entry. This action would enhance the effectiveness of federal and state laboratory-testing capabilities to protect American consumers.
Lead: HHS / FDA, USDA / FSIS
Time Frame: Long Term

Intellectual Property Protection

Recommendation 10 – Strengthen Protection of Intellectual Property Rights (IPR) to Enhance Consumer Safety.

Strong IPR enforcement is essential to the protection of public health and safety. Counterfeit trademarked goods purporting to be made and marketed by someone other than the owner of the mark not only pose a threat to public safety, but undermine confidence in the quality of brand name products. These illegal activities also result in billions of dollars of lost revenue, investment, future sales and growth opportunities and harm legitimate businesses and workers who play pivotal roles in creating, manufacturing, distributing and selling genuine and safe products. The public and private sectors must work in concert to identify infringing and potentially unsafe goods and prevent them from entering the domestic marketplace.

> If a container is packed with counterfeit goods, there is surely a higher likelihood than average that the goods in that container are dangerous in some way.
>
> David Spooner
> Assistant Secretary for
> Import Administration
> Department of Commerce

Patents protect the design, formulae and content of a wide variety of manufactured products, consumer goods and pharmaceuticals. Trademarks protect the brand name of known and trusted companies so that consumers can be sure they are getting the same quality product that they expect to obtain under that mark. When patents are infringed, consumers suffer because infringers create disincentives to the invention of new products and processes. Patent infringement may be accompanied by counterfeiting and trademark infringement. When look-alike knock-off and counterfeit products violate trademarks, consumers cannot be certain of the quality or origin of the knock-off product. In addition, because infringing products are often substandard in quality, they can harm consumers in myriad ways and pose serious health and safety risks. For example, a counterfeit drug may have too little, too much or no active ingredient or contain a toxic contaminant, possibly putting consumers at risk for serious adverse events or worsened health from ineffective treatment of their underlying medical condition.

10.1 *Focus the work of the interagency Strategy Targeting Organized Piracy (STOP) and the United States government-private sector Coalition against Counterfeiting and Piracy Initiative on import-safety issues.* STOP focuses on empowering American innovators to protect better their rights at home and abroad, increasing efforts to seize counterfeit goods at U.S. borders, pursuing criminal enterprises involved in piracy and counterfeiting, working closely and creatively with U.S. industry and aggressively engaging trading partners to join U.S. efforts.

The Coalition Against Counterfeiting and Piracy encourages close cooperation between the public and private sectors to effectively secure supply chains and protect consumers and rights holders.
Lead: Department of Commerce
Time Frame: Short Term

10.2 Expand information-sharing about counterfeit and other goods that infringe IPR among relevant U.S. departments and agencies to identify and target products, manufacturers and distributors with potential safety violations. The International Intellectual Property Enforcement Coordinator, housed at the Department of Commerce, is responsible for disseminating information and coordinating actions on IPR among federal departments and agencies, primarily Commerce, DOJ, USTR, DHS and State. With a new emphasis on ensuring import safety, the Coordinator should extend its outreach and coordination activities to include agencies responsible for import-safety inspections, such as FDA, CPSC and USDA. In addition, with the anticipated increase in private entity certifiers for U.S. safety requirements, it is essential to enhance interagency IPR coordination to include these inspecting agencies.
Lead: Department of Commerce
Time Frame: Short Term

Safety and Intellectual Property
It is critical that the federal government continue to work with trading partners to improve the protection and enforcement of intellectual property rights because counterfeit products can pose significant safety risks.

10.3 Encourage companies that have registered trademarks with the U.S. Patent and Trademark Office (USPTO) to record their registrations with CBP. Industries must record their trademarks with CBP to enable CBP to identify, seize and destroy infringing and potentially unsafe goods.
Lead: Department of Commerce
Time Frame: Short Term

The end goal must be to create the necessary mechanisms that will allow risk assessment and risk management professionals to actively engage with manufacturers and importers in assessing and reducing risks along their supply chains.

SuiMing (Tomi) Hong
AmeriSci Group

Response

In the event that an unsafe import does make its way into the domestic stream of commerce and may or does injure consumers or animals, swift actions must be taken to limit potential exposure and harm.

Recall

Recommendation 11 – Maximize the Effectiveness of Product Recalls.

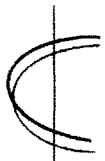
The recall process is the principal tool in the arsenal of response mechanisms to protect consumers from exposure to hazardous products whether the products are domestic or imported. Generally, the manufacturer, distributor, importer or retailer initiates a product recall with the cooperation of the appropriate government agency (e.g., FDA for most foods and CPSC for consumer goods).

11.1 Amend the CPSA to make it unlawful for any manufacturer, distributor or retailer to sell a recalled product knowingly and willfully after the date of public announcement of the recall. Under the CPSA, it is currently legal for such entities to sell a recalled product (other than a product that fails to comply with a mandatory standard or ban) even after the public announcement of the recall. Amending the CPSA will create proper incentives for retailers and distributors to halt sales of recalled products as quickly as possible.
Lead: CPSC
Time Frame: Short Term

11.2 Authorize follow-up recall authority for CPSC. If, after public notice of a voluntary recall, it later comes to the attention of the Commission that products subject to the voluntary recall remain widely available on the market, this provision would allow the agency to act quickly to issue an identical follow-up recall notice without having to consult again with the subject firm. This authority would be particularly helpful in instances of high-volume recalls in which one announcement may prove inadequate to inform the public.
Lead: CPSC
Time Frame: Short Term

11.3 Authorize CPSC to require all recalling firms to provide the name and address of companies that supplied or received the recalled product. Although maintaining thorough and accurate information about product suppliers, manufacturers and distributors is widely viewed as an industry best practice, not all firms maintain such information. Others do not disclose it to the Commission in the event of a recall. With proper authority, the CPSC could require every recalling entity to provide the agency with detailed contact information for all relevant parties across the life cycle

of the recalled product. Granting the CPSC authority to compel such information in times of recall creates an incentive for firms to adopt strong record-keeping practices as a matter of standard business operations.
Lead: CPSC
Time Frame: Short Term



11.4 *Authorize FDA to issue a mandatory recall of food products when voluntary recalls are not effective.* Currently, FDA lacks the authority to require the recall of food, including food it reasonably believes is adulterated and presents a threat of serious adverse health consequences or death. Although market incentives have made the voluntary recall system generally effective, providing mandatory recall authority to FDA when the voluntary system is not successful would ensure that the agency has the ability to compel action in those instances when firms have refused or unduly delayed a voluntary recall of food. The authority would provide for appropriate due process rights for any firm subject to a recall order.
Lead: HHS / FDA
Time Frame: Short term

Federal-State Rapid Response

Recommendation 12 – Maximize Federal-State Collaboration.

The roles of and the resources used by the federal government and the states in import safety are complementary. States possess legislative authority and resources to respond to unsafe imported products within their jurisdiction. The federal government can take steps to interdict unsafe imported goods at ports-of-entry. Should an unsafe product enter domestic commerce, federal departments and agencies often work with state authorities to track it down, seize it, notify the public if it has already been purchased by consumers and impose appropriate penalties on domestic entities who violate U.S. law. Also, both the federal government and states may have access to information relevant to protecting consumers that the other does not possess. For example, federal departments and agencies may have relevant information about the foreign source of the imported product and about the importer. This information can help state officials track down an unsafe imported product within their jurisdiction. On the other hand, state officials may identify an unsafe imported product during transport or at the point-of-sale, if the product does get into the country, and can tip off federal officials to prevent future shipments from entering domestic commerce.

> To achieve comprehensive coordination, state and local governments also have a vital role and must be fully integrated into overall national efforts.
>
> Hallock Northcott,
> American Association of Exporters and Importers

Several federal departments and agencies already collaborate closely with state authorities to protect consumers. For example, FDA has contracts and cooperative agreements with state governments to share information, conduct joint inspections and collaborate on laboratory analyses. Greater mutual leveraging of state and federal resources can further enhance consumer protection.

12.1 *Consider cooperative agreements between the federal inspection agencies and their state counterparts for greater information-sharing.* Such cooperative agreements would not infringe on the statutory authorities of federal or state regulators and would encourage a coordinated effort that would result in a more rapid and effective response. Establishing clear procedures and points-of-contact for information sharing and joint enforcement efforts can further enhance the effectiveness of federal-state actions to limit exposure and potential harm to consumers if an unsafe imported product makes it into domestic commerce.
Leads: HHS / FDA, USDA, CPSC, EPA
Time Frame: Long Term

12.2 *Review admissibility policies to improve the use of evidence and laboratory results from state investigations of imported products.* Currently, there are limitations on the use of state-developed evidence in federal court cases due to the gathering, analysis and retention of such evidence by non-federal government entities. Being able to use this evidence would make it easier for federal departments and agencies to take enforcement actions against bad actors.
Leads: DOJ, HHS / FDA, USDA, CPSC
Time Frame: Short Term

Technology

Technological advancements can help industry, as well as federal and state governments, more effectively respond to safety incidents involving imports.

Recommendation 13 – Expedite Consumer Notification of Product Recalls.

After a manufacturer has recalled an imported product because of safety concerns, it is essential for consumers to receive notification of the recall as quickly as possible. While government and industry work largely in cooperation to enact product recalls, the emergence of new technologies may permit an even more rapid and efficient response.

13.1 *Develop best practices for the use of technologies to expedite consumer notification of recalls.* With advances in product-tracking technologies, such as integrated circuit cards (Smart Cards) and Radio Frequency Identification (RFID), retailers are increasingly capable of learning and anticipating their customers' preferences, both as individuals and

cohorts. Information collected at the point-of-sale, provided voluntarily by consumers in exchange for product discounts and other benefits, has significant potential in the realm of product safety. For example, consumers who voluntarily share their personal contact information with a retailer (email address, telephone number, etc.) also can agree to receive instant recall notification from the seller regarding any of the products they recently purchased at that store. To the extent that the private sector can leverage the use of Smart Cards, RFID and other technologies to expedite consumer notification of emerging or existing product hazards while adequately protecting consumer privacy, the government should support such efforts.
Leads: USDA, HHS / FDA, CPSC
Time Frame: Long Term

Track-and-Trace

Recommendation 14 – Expand the Use of Electronic Track-and-Trace Technologies.

> To be effective, tracking requirements must apply at all points along the production continuum, from point of origin to retail sale, and consumers should be given clear information to use to identify recalled products in their home.
>
> Caroline Smith DeWaal,
> Center for Science in the Public Interest

Traceability is the capacity to identify and track a product or group of products along the import life cycle, including at all points throughout the sourcing, manufacturing and distribution chain. The ability to identify the product source and points of distribution across the import life cycle is of prime importance for the protection of consumers, particularly in the event of a product recall. If unsafe imports are discovered, effective traceability mechanisms can facilitate timely product recovery and reduce the opportunity for harm to occur. Additionally, the capacity to connect the dots and link import life cycle information back to the point of origin enables both government and private-sector actors to provide consumers with targeted and accurate information concerning implicated products. Traceability is also an effective preventive tool in that post-recall information and feedback can be processed to identify and address weaknesses across the import life cycle.

14.1 Work with foreign and domestic industry to encourage the development of best practices for the use of electronic track-and-trace technologies.
Leads: USDA, HHS / FDA, CPSC, DOT
Time Frame: Long Term

Conclusion

This Action Plan creates a roadmap for short-term and long-term improvements in the safety of imported products. The Working Group sets forth 14 recommendations and 50 action steps that are based on the organizing principles and building blocks identified in the Strategic Framework released on September 10, 2007. In addition, at the same time as the release of the Strategic Framework, the Working Group outlined Immediate Actions to be taken by federal departments and agencies to effect meaningful change. Together, the Strategic Framework and this Action Plan provide a national strategy for continually improving the safety of imported products.

Key action steps, which provide the pathway for implementing these recommendations, have each been assigned to lead entities that will be responsible for implementing this Action Plan.

Implementation of the recommendations will require resources, including reallocation of existing resources, as well as trade-offs, to fund these priorities. Additionally, it will require expanded authorities, greater coordination among federal departments and agencies, improved accountability for industry, increased foreign capacity building, greater information-sharing, partnerships with the private sector and the application of new science, to name just some of the activities the federal government must place priority on in coming years. Implementation will also require a collaborative approach by all participants in the import safety life cycle. By doing so, American consumers will be able to continue to enjoy the benefits of the global economy with confidence.

The recommendations in this Action Plan create a path for the United States to complete the shift from an intervention approach to a prevention with verification, risk-based approach that builds safety into the products that reach U.S. consumers. This shift in emphasis can occur by following these recommendations:

1. **Safety Standards:** Create new and strengthen existing safety standards.
2. **Certification:** Verify compliance of foreign producers with U.S. safety and security standards through certification.
3. **Good Importer Practices:** Promote Good Importer Practices.
4. **Penalties:** Strengthen penalties and take strong enforcement actions to ensure accountability.
5. **Foreign Collaboration and Capacity Building:** Make product safety an important principle of our diplomatic relationships with foreign countries and increase the profile of relevant foreign assistance activities.
6. **Common Mission:** Harmonize federal government procedures and requirements for processing import shipments.
7. **Interoperability:** Complete a single-window interface for the intra-agency, interagency and private-sector exchange of import data.
8. **Information Gathering:** Create an interactive import-safety information network.
9. **New Science:** Expand laboratory capacity and develop rapid test methods for swift identification of hazards.
10. **Intellectual Property Protection:** Strengthen protection of intellectual property rights (IPR) to enhance consumer safety.
11. **Recall:** Maximize the effectiveness of product recalls.
12. **Federal-State Rapid Response:** Maximize federal-state collaboration.
13. **Technology:** Expedite consumer notification of product recalls.
14. **Track-and-Trace:** Expand the use of electronic track-and-trace technologies.

Appendix A: Executive Order

Executive Order: Establishing An Interagency Working Group on Import Safety

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to ensure that the executive branch takes all appropriate steps to promote the safety of imported products, it is hereby ordered as follows:

Section 1. Establishment of Interagency Working Group on Import Safety. The Secretary of Health and Human Services shall establish within the Department of Health and Human Services for administrative purposes only an Interagency Working Group on Import Safety (Working Group).

Sec. 2. Membership and Operation of Working Group.

(a) The Working Group shall consist exclusively of the following members, or their designees who shall be officers of the U.S. appointed by the President or members of the Senior Executive Service:

(i) the Secretary of Health and Human Services, who shall serve as Chair;
(ii) the Secretary of State;
(iii) the Secretary of the Treasury;
(iv) the Attorney General;
(v) the Secretary of Agriculture;
(vi) the Secretary of Commerce;
(vii) the Secretary of Transportation;
(viii) the Secretary of Homeland Security;
(ix) the Director of the Office of Management and Budget;
(x) the United States Trade Representative;
(xi) the Administrator of the Environmental Protection Agency;
(xii) the Chairman of the Consumer Product Safety Commission; and
(xiii) other officers or full-time or permanent part-time employees of the United States, as determined by the Chair, with the concurrence of the head of the department or agency concerned.

(b) The Chair shall convene and preside at meetings of the Working Group, determine its agenda, and direct its work. The Chair may establish and direct subgroups of the Working Group, as appropriate to deal with particular subject matters, that shall consist exclusively of members of the Working Group. The Chair shall designate an officer or employee of the Department of Health and Human Services to serve as the Executive Secretary of the Working Group. The Executive Secretary shall head any staff assigned to the Working Group and any subgroups thereof, and such staff shall consist exclusively of full-time or permanent part-time Federal employees.

Sec. 3. Mission of Working Group. The mission of the Working Group shall be to identify actions and appropriate steps that can be pursued, within

existing resources, to promote the safety of imported products, including the following:
(a) reviewing or assessing current procedures and methods aimed at ensuring the safety of products exported to the United States, including reviewing existing cooperation with foreign governments, foreign manufacturers, and others in the exporting country's private sector regarding their inspection and certification of exported goods and factories producing exported goods and considering whether additional initiatives should be undertaken with respect to exporting countries or companies;

(b) identifying potential means to promote all appropriate steps by U.S. importers to enhance the safety of imported products, including identifying best practices by U.S. importers in selection of foreign manufacturers, inspecting manufacturing facilities, inspecting goods produced on their behalf either before export or before distribution in the United States, identifying origin of products, and safeguarding the supply chain; and

(c) surveying authorities and practices of Federal, State, and local government agencies regarding the safety of imports to identify best practices and enhance coordination among agencies.

Sec. 4. Administration of Working Group. The Chair shall, to the extent permitted by law, provide administrative support and funding for the Working Group.

Sec. 5. Recommendations of Working Group. The Working Group shall provide recommendations to the President, through the Assistant to the President for Economic Policy, on the matters set forth in section 3 within 60 days of the date of this order, unless the Chair determines that an extension is necessary. The Working Group may take other actions it considers appropriate to promote the safety of imported products

Sec. 6. Termination of Working Group. Following consultation with the Assistant to the President for Economic Policy, the Chair shall terminate the Working Group upon the completion of its duties.

Sec. 7. General Provisions.
(a) Nothing in this order shall be construed to impair or otherwise affect (i) authority granted by law to a department, agency, or the head thereof, or (ii) functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals.
(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
(c) This order is not intended to, and does not, create any right, benefit, or privilege, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH
THE WHITE HOUSE,
July 18, 2007.

Appendix B : Immediate Actions Memorandum
September 10, 2007

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

September 10, 2007

The President
The White House
Washington, D.C. 20500

Re: Interagency Working Group on Import Safety

Dear Mr. President:

On behalf of the Interagency Working Group on Import Safety and in accordance with Executive Order 13439, I am pleased to submit this report, *Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety.*

Accompanying this report is a listing of *Immediate Actions* that the Working Group recommends that the Federal government implement without delay to protect American consumers. These recommendations will be followed by an Action Plan in mid-November 2007, which will set out a roadmap with short- and long-term recommendations for improving import safety.

I want you to know of my appreciation for the assistance of all of your designees in this process. Their contributions have been exceptional.

As a Working Group, we provide the Strategic Framework and Immediate Actions with a belief that these changes will make the most effective use of our resources and provide the greatest protection to American consumers over the long term.

Thank you for the opportunity to serve.

Sincerely,

Michael O. Leavitt
Secretary, Department of Health and Human Services

Listing of Immediate Actions

1. **Improve collaboration and information sharing with the private sector to improve the safety of imports.**

   A wide range of products that could potentially threaten the health and safety of U.S. consumers are imported every day. Due to the vast volume of imported products, it is impossible to ensure safety simply by increasing government inspections. Rather, engagement with the importing community must be enhanced to gain insights from the owners and operators of the commercial import infrastructure through which all imported products reach American consumers, and to share best practices among this community.

   To conduct this outreach and improve collaboration with the importing community, the agencies should expand on existing public-private relationships, such as COAC (Commercial Operations Advisory Committee), TSN (Trade Support Network), F&ASCC (Food and Agriculture Sector Coordinating Council), ITACs and ATACs (Industrial Trade and Agricultural Trade Advisory Committees), and other groups, to seek and share the importing community's recommendations and best practices with the objective of enhancing import safety and promoting comprehensive supply chain verification.

   Recommendations for implementation of this action will be included in the Working Group's forthcoming Action Plan.

2. **Interoperability Acceleration – Instruct Executive Agencies to Complete Their Identification of Technical, Business and Legal Requirements for Operating Within the Automated Commercial Environment/International Trade Data System.**

   The Security and Accountability for Every ("SAFE") Port Act of 2006 requires all Federal agencies that license, permit, or certify imported products to participate in the International Trade Data System (ITDS), a "single-window" system for reporting imports and exports electronically. ITDS will operate as a feature of U.S. Customs and Border Protection's (CBP) trade data processing system called the Automated Commercial Environment (ACE), which is currently under development. Functional capabilities within ACE are being implemented in stages, with full operability expected in 2009. Currently, 34 Federal agencies, referred to as Participating Government Agencies (PGAs), are at varying stages in integrating into ITDS.

   In order to accelerate implementation of ITDS, the Office of Management and Budget should issue a directive to PGAs requiring that within 60 days of the directive they establish or refine their Implementation Plan setting deadlines for developing, reviewing and finalizing conceptual operating plans (Concept of Operations),

memoranda of understanding for the ITDS interface, and a set of technical and business requirements for identifying any program and system modifications needed to support the interface. This would include considerations for the budget process. OMB should give special priority to import safety agencies for this task in the budget process

Further, in order to accelerate implementation of ITDS, the Office of Management and Budget should direct that CBP, within 60 days, establish or refine its Implementation Plan setting deadlines to:

- Include information currently reported by importers and carriers to CBP in the ACE Data Warehouse, where it can be accessed by other agencies.
- Advise other agencies with an import safety mission how they can take full advantage of current ITDS capabilities and deepen their engagement in ITDS development
- Implement World Customs Organization Data Model messages (new international international standard for customs reporting), which could provide a platform for electronic reporting of health and safety information in advance of the current ITDS production schedule.

In addition, all PGAs are instructed to:

- Within their fiscal year 2009 budget submissions, identify the budgetary resources needed to support the ACE/ITDS interface. Within 60 days, designate a senior executive responsible for implementing the ACE/ITDS interface.

  Within 60 days, designate a senior executive responsible for implementing the ACE/ITDS interface.

Participating Government Agencies (PGAs)

- AMS - Agricultural Marketing Service (Agriculture)*
- APHIS - Animal and Plant Health Inspection Service (Agriculture)*
- ATF - Bureau of Alcohol, Tobacco, Firearms and Explosives (Justice)*
- BIS – Bureau of Industry and Security (Commerce)
- BLS - Bureau of Labor Statistics (Labor)
- BTS - Bureau of Transportation Statistics (Transportation)
- CDC- Center for Disease Control (Health and Human Services)*
- Census – U.S. Census Bureau (Commerce)
- CPSC – Consumer Product Safety Commission*
- DEA – Drug Enforcement Administration (Justice)*
- EPA - Environmental Protection Agency*
- FAA - Federal Aviation Administration (Transportation)*
- FAS – Foreign Agricultural Services (Agriculture)
- FCC - Federal Communications Commission*
- FDA - Food and Drug Administration (Health and Human Services)*

- FMC - Federal Maritime Commission
- FMCSA - Federal Motor Carrier Safety Administration (Transportation)*
- FSIS - Food Safety and Inspection Service (Agriculture)*
- FTZB - Foreign Trade Zones Board (Commerce)
- FWS - Fish and Wildlife Service (Interior)*
- GIPSA – Grain Inspection, Packers and Stockyards Administration (Agriculture)
- IA - International Trade Administration–Import Administration
- (Commerce)
- IRS - Internal Revenue Service (Treasury)
- ITC – International Trade Commission
- MARAD - Maritime Administration (Transportation)
- NHTSA – National Highway Traffic Safety Administration (Transportation)*
- NMFS – National Oceanic Atmospheric Administration / National Marine Fisheries Service, Office for Law Enforcement (Commerce)*
- NRC - Nuclear Regulatory Commission*
- OFAC - Office of Foreign Assets Control (Treasury)
- OFE – Office of Fossil Energy (Energy)
- OFM - Office of Foreign Missions (State)
- State – Logistics Management (State)
- TTB - Alcohol and Tobacco Tax and Trade Bureau (Treasury)*
- USACE - Army Corps of Engineers (Defense)

*Agencies designated by the Board of ITDS as import safety agencies due to their roles in licensing, certifying, and permitting import shipments.

3. **Global Collaboration – Instruct agencies to develop and increase international cooperation and collaboration.**

   The Department of State (State) has contacted host governments in 39 countries that are top exporters of food and consumer products to the United States to seek information on how various countries handle import safety issues. In the coming weeks, State, the Office of the United States Trade Representative (USTR), and other interested agencies will analyze the responses to these inquiries and meet to determine appropriate next steps.

   As part of these next steps, State and USTR should coordinate with other Working Group members to determine whether appropriate international and regional organizations could be helpful in hosting international conferences or other actions to promote product safety, in order to generate high-level global attention to a worldwide problem. Such events could provide a forum to exchange information on effective product safety practices, identify opportunities for regulatory capacity building, and promote science-based regulation, consistent with U.S. law and our international obligations

Recommendations for implementation of this action will be included in the Working Group's forthcoming Action Plan.

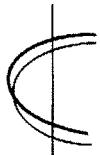
4. **Agreements with Foreign Governments – Instruct agencies to catalog on-going and planned import safety-related agreements (bilateral and multilateral) with foreign governments. In addition, require agencies to meet within 45 days and then on a regular basis to discuss negotiations underway or that are anticipated and share lessons learned.**

   Various U.S. government agencies work with foreign governments to conclude and implement bilateral and multilateral agreements to improve import safety. In many cases, the agency that has expertise in a particular facet of import safety takes the lead in the negotiations. The resulting agreements, however, may affect the jurisdiction, operations, and resources of other agencies. Therefore, coordination among all the relevant agencies is necessary to ensure that all such agreements are as effective as possible and can be fully implemented.

   Currently, coordination procedures vary depending on the nature of the agreement. Despite the various existing means for coordination, interagency work on import safety negotiations with foreign governments can be improved. In particular, efforts should be made to increase interagency awareness of agencies' ongoing and planned discussions with foreign governments regarding import safety agreements. In addition, the current coordination processes should be modified to provide a forum for agencies to share successful strategies and approaches with other agencies that could benefit from their experiences. Earlier and improved coordination will help ensure that agreements fully benefit from relevant agencies' experiences, avoid duplicative or counterproductive efforts, and generally improve the negotiating position of the U.S. government.

   To this end, as an immediate action, agencies should be required to catalog ongoing and planned discussions with foreign governments regarding import safety. Until the Action Plan is issued, the Department of Commerce should host regular advisory meetings for these agencies to share information about their efforts, experiences and concerns. This process is not a review and would in no way supplant or delay the TPSC and C-175 processes, or any other on-going relevant inter-agency process. International cooperation regarding law enforcement or other similar activities would not be subject to these meetings.

Appendix C: Recent Actions and Current Plans to Protect American Consumers



As directed by the President, all departments and agencies have been reviewing and assessing current procedures, authorities, outreach efforts and international cooperation initiatives to enhance the safety of imported products. They have met with foreign governments, foreign manufacturers and others in the exporting country's private sector, as well as with producers, importers, retailers, trade associations, consumer groups and others in the U.S. importing community.

Based on these reviews and meetings, the departments and agencies have already taken numerous actions to protect American consumers. Many more initiatives to enhance the safety of imported products are underway and will be completed in the coming months. This appendix summarizes significant recent accomplishments and important actions that will be completed within the first 200 days of issuing this Action Plan.

The actions are structured according to the organizing principles from the Strategic Framework and the recommendations included in this Action Plan.

Prevention with Verification

Safety Standards

- **Food Protection Plan.** FDA has developed a Food Protection Plan that addresses both food safety and food defense for domestic and imported products, including food protection from production to consumption. The Plan will be phased in over the coming months and is integrated with the Administration's Import Safety Strategic Framework and Action Plan.

Certification

- **NOAA Seafood Inspection Program.** As of October 24, 2007, the Department of Commerce's National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program has inspected and certified seven seafood processing plants in China and has plans to inspect another 12 plants. There are a number of other plants in the queue to be inspected.

- **Improved Compliance with Toxic Substance Control Standards.** EPA's Office of Prevention, Pesticides and Toxic Substances has been developing a Toxic Substance Control Act (TSCA) "Section 13 Import Compliance Checklist" as a compliance assistance tool to help chemical importers and government inspectors better understand import certification requirements. When finalized, the Checklist will be posted on various Web sites and disseminated in other ways.

- **Seafood Inspectors Stationed in Other Asian Countries.** NOAA is in the process of stationing an inspector full time in Hong Kong and has plans to put inspectors in other countries that export large volumes of seafood to the United States.

- **New Zealand Meat Certification.** USDA's Food Safety and Inspection Service (FSIS) began reprogramming its import inspection data system to enable an electronic data transfer of certifications for meat export shipments from New Zealand. This will constitute verification that importers have presented New Zealand import shipments for FSIS inspection as required by law. Full electronic certificate exchange capability is expected to be operational by the end of 2007 and will be extended to include Australia and Canada during 2008.

- **Accreditation of Private Labs.** FDA will issue guidance by mid-2008 that would set standards for the sampling and testing of imported products, including the use of accredited private laboratories submitting data to FDA to assist in evaluating whether an appearance of a violation may be resolved. Increased confidence in the sampling techniques and methodologies used by accredited laboratories and in the data they submit may allow FDA to base decisions on abbreviated laboratory packages from accredited laboratories, expedite review of the information in those packages and facilitate admissibility decisions.

Foreign Cooperation and Capacity Building

- **Safety Agreement with China on Toys, Fireworks and Electrical Products.** Meetings held in September 2007 between CPSC and its counterpart, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) of the People's Republic of China resulted in a renewed Memorandum of Understanding (MOU) related to the promotion of safety for target products—children's toys, fireworks, cigarette lighters and electrical products.

- **Memoranda of Agreements with China on Food, Drugs, Medical Devices and Animal Feed.** HHS/FDA is negotiating binding agreements with the Chinese government to enhance regulatory cooperation in the area of drugs, medical devices, food and animal feed. These agreements will protect the safety and health of consumers and animals in the United States and in China.

- **Motor Vehicle Safety Agreement with China**. On September 12, the Department of Transportation's National Highway Traffic Safety Administration (NHTSA) signed a Memorandum of Cooperation with China aimed at increasing cooperation in the areas of motor

vehicle regulation and safety. Both sides indicated a willingness to work together to address issues related to the safety of Chinese motor vehicles and equipment (including tires and automotive fuses) intended for export to the United States.

- **Tire Safety Standards Talks with China.** From September 11 through September 18, NHTSA staff with expertise in NHTSA's tire standards and enforcement process attended the Chinese International Tire Exposition in Shanghai and met with China's technical experts on tire issues in Hangzhou. At both locations, NHTSA representatives made detailed presentations on the agency's standards and enforcement process. The presentations were well received by the many representatives of the Chinese tire industry who participated in these sessions. NHTSA's delegation also obtained information that will be useful in designing strategies to help deter and detect the shipment of noncompliant or defective tires from China to this country.

- **Seafood Inspection Agreement with China.** NOAA's National Marine Fisheries Service (NMFS) has begun discussions with China's Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) on an MOU to improve information transfer and to increase the traceability of products. The MOU would establish a notification system whereby each party would alert the other in the event that a problem is detected with seafood being imported from China. Drafts have been exchanged and a final agreement is anticipated in early 2008.

- **Foreign Training on United States Safety Standards for Meat, Poultry and Eggs.** In July 2007, USDA and FDA conducted a seven-week training program for Chinese inspection officials. FSIS also conducted outreach to foreign government inspection officials regarding FSIS import requirements for meat, poultry and egg products. FSIS provided technical assistance to the Austrian government regarding U.S. import requirements for ready-to-eat products, to Mexico regarding microbiological testing procedures and to the governments of Bosnia-Herzegovina, Namibia and Thailand about U.S. import requirements in general.

- **United States-Europe Consumer Protection Talks.** On October 14, 2007, the Trans-Atlantic Consumer Dialogue was held at the State Department. Topics included the review of the respective regulatory impact assessment guidelines on trade and investment and their application, reduction in barriers on trade in chemicals, controlling hazardous toy and consumer product imports, recognition of Supplier's Declaration of Conformity for electrical equipment and other topics of concern in the ongoing trans-Atlantic dialogue.

- **Security and Prosperity Partnership (SPP) priority on Safe Food and Products.** In August, President Bush, President Calderon of Mexico and Prime Minister Harper of Canada pledged to strengthen trilateral cooperation and mechanisms within the region, build on current standards and practices and work with our trading partners outside of North America to identify and stop unsafe food and products before they enter our countries.

- **Product Safety in Standards Dialogues.** The Department of Commerce is engaging in standards dialogues with key trade partners like Brazil, the European Commission and India. Product safety issues were discussed with India on October 25 and with the European Union on October 29. These dialogues encourage information exchange on policies, procedures and processes to ensure the safety of imported products.

- **International Food Safety Standards Work in Codex Alimentarius.** The Department of Commerce, State, EPA, USDA, FDA and USTR are actively engaged in international food safety standards development work in Codex Alimentarius. Codex already has a significant inventory of standards and guidelines that address food hygiene, food labeling, food import and export certification and inspection systems, contaminants in food and other areas. The United States is considering what gaps exist in food safety standards that Codex might address through new work activities.

- **China Joint Commission on Commerce and Trade (JCCT) Pharmaceutical Task Force.** The JCCT provides ongoing workshops to the Chinese government on anti-counterfeiting and manufacturing best practices for pharmaceuticals. Accomplishments have included direct input into the China State Food and Drug Administration's update of its drug registration review process.

- **China Joint Commission on Commerce and Trade (JCCT) Medical Devices Task Force.** The Department of Commerce and FDA provide ongoing training to the Chinese government on the use of quality systems to ensure the safety of manufactured products, including conducting product recalls for medical devices.

- **Pharmaceutical anti-counterfeiting activity under the United States-India High Technology Cooperation Group's Biotechnology & Life Sciences Working Group.** This group organizes activities to fight the counterfeiting of pharmaceuticals and addresses the regulation of active pharmaceutical ingredients

to prevent the production of counterfeit medicines. In August 2007, this group discussed with Indian government officials the need to cooperate with the international community in stopping the production and export of counterfeit pharmaceuticals and the need to regulate active pharmaceutical ingredients.

- **APEC Anti-Counterfeit and Regulatory Harmonization Seminars on Medical Devices.** DOC and FDA are organizing a series of capacity-building seminars for Asia and Latin America focused on stopping the spread of counterfeit health products and promoting regulatory harmonization for medical devices. The first anti-counterfeit seminar will take place in Singapore in January 2008; the first regulatory harmonization seminar will take place in Kuala Lumpur in March 2008. Subsequent seminars will take place throughout 2008 and early 2009 in Asia and Latin America. Participants will include pharmaceutical and medical device regulators, custom and law enforcement officials, health professionals and industry representatives.

- **Motor Vehicle Safety Seminars with Chinese Companies.** In late 2007 or early 2008, NHTSA plans to send senior officials to China to meet with the relevant government departments and agencies, trade associations and companies to discuss how NHTSA's standards and enforcement process apply to exports intended for sale in the United States. NHTSA intends to reach those companies already engaged in exporting motor vehicle equipment and those that have announced plans to export motor vehicles to the United States in the next two years. NHTSA will also look for opportunities to enter into more detailed agreements with the Chinese government on cooperative methods to help ensure that imports are compliant with NHTSA standards.

- **Cooperative Agreement with China on Environmental Requirements.** In April 2007, EPA met with China's AQSIQ and other groups and agreed to draft an EPA-AQSIQ MOU to exchange information on environmental requirements and cooperate to help ensure compliance.

- **Cooperation on Enforcement of Environmental Laws in North America.** An understanding was recently reached among EPA, Canadian and Mexican environmental law enforcement officials to share information about noncompliant imports entering the borders of any of the countries.

- **North American Development of Enforcement Training to Ensure Legal Imports.** In September 2007, representatives from environmental agencies of the United States, Canada and Mexico, reviewed an electronic training module on ozone-depleting substances. At the same time, the officials approved the creation of a similar module for hazardous waste.

- **Outreach on Import Safety through Diplomatic Channels.** The State Department's Bureaus of Economic, Energy and Business Affairs and International Information Programs developed an outreach plan to reach foreign audiences on import safety. To date, import safety articles have already been published in international newspapers; more are expected over the near term. In August 2007, the Department of State sent cables to all overseas posts to provide them with information about import safety and the role of the Interagency Working Group on Import Safety for discussion with governments and the private sector.

- **Negotiation and Capacity Building through Trade Channels.** An integral part of U.S. free trade agreements are commitments to address sanitary and phytosanitary (SPS) [12] issues. In the past year, USTR concluded free trade agreements with Peru, Colombia, Panama and Korea, each of which includes a specific SPS chapter that has as a principal objective the protection of human and animal health. In particular, the SPS chapters provide for the establishment of a standing committee of the parties to enhance cooperation and consultation on SPS matters and improve understanding of each other's SPS requirements. These agreements also provide for capacity building and technical assistance in SPS activities.

- **Anti-Counterfeiting Trade Agreement.** On October 23, 2007, USTR announced that the United States and some of its key trading partners will seek to negotiate an Anti-Counterfeiting Trade Agreement. Anti-counterfeiting efforts will help to improve the safety of imported products.

- **International Dialogues.** The Department of State, Department of Commerce, USDA, USTR, HHS and other federal departments and agencies are encouraging the inclusion of import safety in regional and international dialogues.

    - Import safety will be discussed at the United States-European Union High Level Regulatory Cooperation Forum in November and may also be taken up by the Transatlantic Economic Council, which is also meeting in November.

12 An SPS measure is generally any measure applied to protect human, animal or plant life or health from risks arising from pests, diseases or adulterants or contaminants in food feed.

- At the Asia-Pacific Economic Cooperation (APEC) Summit in September, leaders agreed "to develop initiatives in the coming year that effectively address problems related to import safety in ways that do not hinder trade." There are a number of specific project proposals underway, including one by China to promote information sharing to improve "food safety systems" and another to address Hazard Analysis and Critical Control Points (HACCP).
- USDA has indicated it will fund food safety related workshops for APEC. The primary goal of these workshops would be to raise awareness of, engagement in and compliance with international food safety standards-setting bodies, such as Codex Alimentarius, World Organization for Animal Health (OIE) and the International Plant Protection Convention.
- The Association of Southeast Asian Nations (ASEAN) has endorsed creating a Coordinating Committee on Consumer Protection at its August meeting and is in communication with officials at the CPSC, USDA, FDA and the Federal Trade Commission.

Intervention

Common Mission

- **Enhanced Interagency Cooperation on Animal and Plant Inspections.** USDA's FSIS and USDA's Animal and Plant Health Inspection Service (APHIS) continued monthly conference calls to discuss key import and export issues of concern and to resolve technical problems between the agencies. Recently, participation was expanded to include representatives from the Food and Drug Administration and U.S. Customs and Border Protection.

- **Enhanced Cooperation on Egg Product Safety.** USDA agencies (FSIS, AMS and APHIS) coordinated potential product code systems in use by FDA and the Global Safety Initiative that might further identify USDA-regulated animal, egg and plant products in ITDS/ACE. The agencies currently responsible for regulating the import of eggs and egg products—FDA, APHIS, FSIS, CBP and AMS—are currently identifying product codes to provide clarity in classifying imported products under the Harmonized Tariff Codes.

- **Cooperation on Counterfeits.** DOC's International Trade Administration (ITA) Office of Intellectual Property Rights is

collaborating with CPSC to create a Counterfeit Alert System that would refer reports of counterfeits received by CPSC's hotline to DOC's Stop Fakes hotline.

Interoperability

- **Public Health Information System.** On September 27, the Food Safety and Inspection Service (FSIS) awarded a contract for development of a new corporate data warehouse called the Public Health Information System, which will support a user interface for imports and exports. FSIS will develop, test and launch the system. This includes establishing an electronic connection with CBP's ACE/ITDS system and importers for processing imported meat, poultry and egg product shipments.

- **USDA Harmonization with Trade Data System.** USDA's Agricultural Marketing Service (AMS) and APHIS made important progress in establishing an interface with ACE/ITDS. AMS completed import-related business processes, drafted a Concept of Operations and Memorandum of Understanding with CBP and engaged a contractor to identify areas where its connection with ACE/ITDS can be optimized. APHIS submitted its Concept of Operations and Memorandum of Understanding to CPB on October 10. USDA's Grain Inspection, Packers and Stockyards Administration began the ITDS process with CBP on October 30, 2007.

- **EPA Harmonization with Trade Data System.** Building on previous work with CBP and other relevant federal agencies on the development of the single window import-export data system, EPA has accelerated steps in order to become interoperable with ACE/ITDS. EPA is developing business processes and requirements to exchange data between six EPA programs and ACE/ITDS. EPA identified the Chief Information Officer as the executive level representative; assigned EPA's internal Exchange Network Subcommittee as the governance body; established a project management/implementation team structure; is preparing a project implementation plan for submission to OMB on November 12, 2007 and is revising a concept of operations document for submission to CBP in December 2007. EPA is leveraging the Central Data Exchange and Exchange Network technology which the Agency currently uses to exchange data with all 50 states and seven Indian Tribes.

Response

Vigorous Enforcement of Safety Statutes

- **Marking Rule to Prevent Port-Shopping.** By mid-2008, FDA will issue a proposed rule that would require imported food that has been refused entry to be marked "United States: Refused Entry." Such marking would help prevent the introduction of unsafe food into the United States through port-shopping, a practice whereby importers attempt to gain entry through a port after the goods have been refused at another.

- **Criminal Prosecution of Counterfeit Drug and Illegal Substance Offenders.** FDA, CBP and DOJ are continuing vigorous enforcement of statutes banning trade in counterfeit and illegal products. For example, DOJ recently prosecuted an Ohio man charged in online pharmacy conspiracy for selling counterfeit drugs (Viagra, Cyalis, Levitra) shipped from such countries as Pakistan, India and Great Britain. The agencies also collaborated in an international law enforcement operation targeting the underground manufacture of anabolic steroids. The operations have led to 124 arrests nationwide to date and the dismantling of approximately 100 illegal sites that aided in the manufacture and distribution of anabolic steroids, prescription medicines, counterfeit drugs and chemical precursors originating from approximately 30 rogue laboratories in China.

Appendix D: List of Acronyms and Abbreviations

Acronyms	
ACE	Automated Commercial Environment
AMS	Agricultural Marketing Service
APEC	Asia-Pacific Economic Cooperation
APHIS	Animal and Plant Health Inspection Service
AQSIQ	Administration of Quality Supervision, Inspection and Quarantine
ASEAN	Association of Southeast Asian Nations
ASISA	Aviation Safety Information Sharing and Analysis
ATS	Automated Targeting System
COAC	Commercial Operations Advisory Committee
CBP	Customs and Border Protection
CPSA	Consumer Product Safety Act
CPSC	Consumer Product Safety Commission
C-TPAT	Customs Trade Partnership Against Terrorism
DHS	Department of Homeland Security
DOC	Department of Commerce
DOJ	Department of Justice
DOT	Department of Transportation
eLEXNET	Electronic Laboratory Exchange Network
EOP	Executive Office of the President
EPA	Environmental Protection Agency
EPIA	Egg Products Inspection Act
FAA	Federal Aviation Administration
FDA	Food and Drug Administration
FDCA	Federal Food, Drug and Cosmetics Act
FERN	Food Emergency Response Network
FMIA	Federal Meat Inspection Act
FSIS	Food Safety and Inspection Service
GIDEP	Government Industry Data Exchange Program
GSI	Global Safety Initiative
HACCP	Hazard Analysis and Critical Control Points
HHS	Department of Health and Human Services
HTS	Harmonized Tariff Schedule
ICAO	International Civil Aviation Organization
IIP	International Information Programs
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
IPR	Intellectual Property Rights
ITA	International Trade Administration
ITDS	International Trade Data System
MOU	Memorandum of Understanding
NHTSA	National Highway Traffic Safety Administration
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NTC	National Targeting Center

OASIS	Operational and Administrative System for Import Support
OMB	Office of Management and Budget
PHMSA	Pipeline and Hazardous Materials Safety Administration
PPIA	Poultry Products Inspection Act
RFID	Radio Frequency Identification
SAFE Port	Safety and Accountability for Every Port Act
SCC	Food and Agriculture Sector Coordinating Council
SDS	Standard Data Set
SEDS	Standard Establishment Data Service
SFDA	China State Food and Drug Administration
SIP	Seafood Inspection Program
SPP	Security and Prosperity Partnership
State	Department of State
STOP	Strategy Targeting Organized Piracy
TACD	Trans-Atlantic Consumer Dialogue
TIA	U.S. Toy Industry of America
Treasury	Department of Treasury
TSCA	Toxic Substance Control Act
USDA	Department of Agriculture
USPTO	U.S. Patent and Trademark Office
USTR	U.S. Trade Representative
Working Group	Interagency Working Group on Import Safety

Appendix E: Working Group Designees and Staff

Interagency Working Group on Import Safety Designees

Secretary Michael O. Leavitt, Department of Health and Human Services, Chair of the Interagency Working Group

Al Hubbard, Assistant to the President for Economic Policy and Director, National Economic Council

Dan Price, Deputy National Security Advisor for Economic Affairs

Andrew C. von Eschenbach, Commissioner, Food and Drug Administration, Department of Health and Human Services

Dan Sullivan, Assistant Secretary for Economic, Energy and Business Affairs, Department of State

Alan Holmer, Special Envoy for China and the Strategic Economic Dialogue, Department of Treasury

John O'Quinn, Deputy Associate Attorney General, Department of Justice

Richard Raymond, Under Secretary for Food Safety, Department of Agriculture

David Spooner, Assistant Secretary for Import Administration, Department of Commerce

Jeff Shane, Under Secretary for Policy, Department of Transportation

Jeff Runge, Acting Assistant Secretary for Health Affairs, Department of Homeland Security

Robert Shea, Associate Director for Management, Office of Management and Budget

Warren Maruyama, General Counsel, U.S. Trade Representative

Jim Gulliford, Assistant Administrator for Prevention, Pesticides and Toxic Substances, Environmental Protection Agency

Quin Dodd, Chief of Staff, Consumer Product Safety Commission

Interagency Working Group on Import Safety Staff

Jerry Regier, Executive Secretary for the Working Group, Department of Health and Human Services

Jeff Shuren, Food and Drug Administration

Cathy Sauceda, Department of Homeland Security

John Menard, Department of State

Bob Tuverson, Department of Agriculture

Karen Stuck, Department of Agriculture

Stephen Claeys, Department of Commerce

Bernard Carreau, Department of Commerce

Randy Pate, Department of Health and Human Services

Rob Raffety, Consumer Product Safety Commission

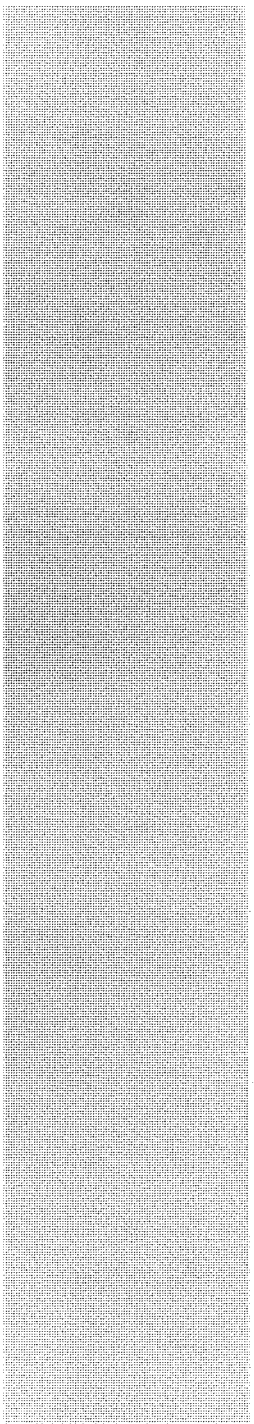
Celesia Gouhari, Department of Health and Human Services

Natalie Gochnour, Department of Health and Human Services

Erik Mettler, Food and Drug Administration

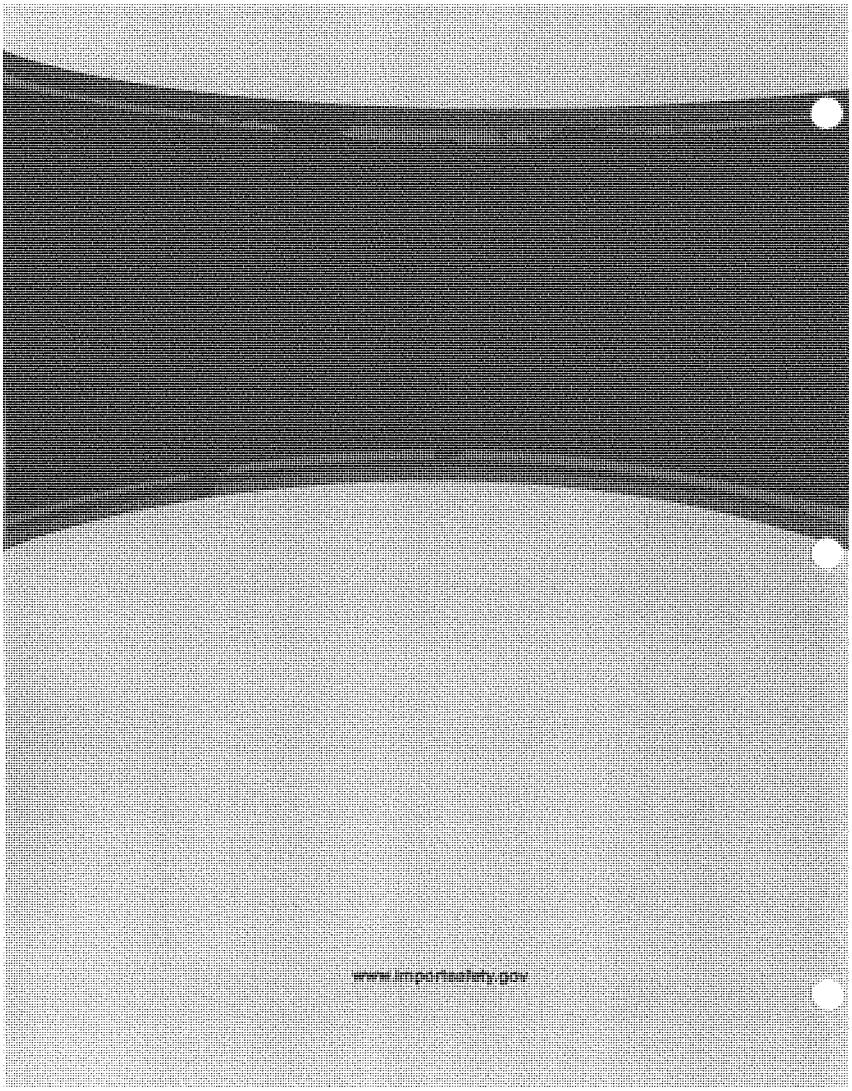
John Herrmann, Executive Office of the President

John Cobau, Executive Office of the President



No import-safety system can succeed without collaboration from everyone involved. We share a common interest in import safety and this Action Plan will guide our collective actions moving forward.

Secretary Michael O. Leavitt
Chair, Interagency Working Group on Import Safety


www.importsafety.gov

National Antimicrobial Resistance Monitoring System (NARMS) Program Review

Conducted by:

External Subcommittee of the
Food and Drug Administration (FDA) Science Advisory Board

Submitted to:
FDA Science Advisory Board
Draft
May 25, 2007

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EXECUTIVE SUMMARY

A group of common themes emerged from the deliberations of the NARMS Subcommittee. These themes included: (1) the need for an improved, statistically valid, and rigorous sampling strategy; (2) timeliness of reporting and reports; (3) harmonization of data; and (4) the creation of a contemporary surveillance platform that would enable participants to conduct hypothesis-driven research, add value, and improve the utilization of data to better achieve the objectives of the NARMS program.

In addressing the four specific questions posed to the Subcommittee, another group of key findings were developed that included the following: (1) The current group of sampling strategies for the various components of NARMS were all found to have degrees of bias. Thus, there is a need to transition these strategies to a group of national, random sampling strategies, including a methodology to better assess antimicrobial resistance in the intestinal flora of truly healthy individuals. When not feasible, data should be further stratified, or sampling should be limited and focused on specific hypothesis-driven research; where sampling biases cannot be corrected, the methodology should be designed as an early warning system for emerging resistance. (2) The Subcommittee strongly encouraged the further development and expansion of a NARMS research portfolio with an emphasis on hypothesis-driven and more collaborative research; there should also be a special emphasis on elucidating the mechanisms of transportation of resistance genes and bacteria across the farm-to-fork continuum and the resultant human infections and illnesses. (3) There was unanimity in support of creating a real-time, web-based, integrated database that would permit generating both participant-specific and collective reports and analyses. In addition, reports must be more timely and accessible, yet they must also be able to accommodate potentially confidential data such as when data on drug usage and exposures are captured in the future. (4) The Subcommittee concluded that the global expansion of NARMS or NARMS-type programs is a critical imperative. Antimicrobial resistance is a growing global issue that demands more international training and intervention; the NARMS program could be used as a model activity for international organizations and other countries.

The Subcommittee was especially pleased with the progress and growing acceptance of the NARMS program over the last decade. The program has evolved into a mission-critical tool for FDA, and the collaborative relationship among the agency participants is an excellent model for other government programs. New pilot projects have proven worthwhile and merit further development, and the on-farm data can help to better link the human and animal health interface and benefit both. The Subcommittee believes that the NARMS activities deserve to be considered as high priorities as agencies struggle with difficult funding decisions. In addition to addressing the pertinent findings, the Subcommittee strongly believes that the NARMS participants should develop an aggressive 10-year plan with new stretch goals using wide public involvement. It is an appropriate time to not only consider program improvements, but to also consider a longer planning horizon to ensure that the NARMS program becomes more strategic, encompassing, and commensurate with the growing global problem of antimicrobial resistance and future animal and public health risks and challenges.

External Subcommittee Review of FDA/NARMS Program

Summary of Charge

The Science Board Advisory Committee to the Federal Drug Administration (FDA) established a subcommittee to evaluate the National Antimicrobial Resistance Monitoring Systems (NARMS) program and to address four questions relevant to the continued success of the program. The four questions included the following:

1. Are there inherit biases in the sampling strategies employed in NARMS? If so, how can they be improved to ensure that the data and interpretation are scientifically sound given current resources?

2. Are there epidemiological and/or microbiological research studies that would better serve the goals of NARMS and the regulatory work of FDA?

3. Are current plans for data harmonization and reporting appropriate? If not, what are the top priorities for advancing harmonized reporting?

4. Are the current NARMS international activities adequate to address the worldwide spread of antimicrobial-resistant food-borne bacteria?

Panel Approach

The Subcommittee (members listed in Appendix 1) met on April 10-11, 2007, in Rockville, Maryland, and heard presentations from the three federal partners of NARMS: FDA, Centers for Disease Control and Prevention (CDC), and United States Department of Agriculture (USDA). (Federal agency presenters are listed in Appendix 2). In addition, the Subcommittee also heard presentations from members of the public during a public hearing held as part of the program review (public presenters are listed in Appendix 3). This report will be submitted to the FDA Science Advisory Board on June 14, 2007, for their review and disposition.

Introduction

NARMS is a national collaborative network involving the FDA, CDC, and USDA. The system was developed to monitor changes in susceptibility/resistance of select zoonotic bacterial pathogens and commensal organisms recovered from animals, some retail meats, and humans to antimicrobial agents of public health and animal health significance.

NARMS was started in 1996 in response to a public health concern based on the recognition of the growing problem of antimicrobial resistance. The system has evolved over the last decade growing in stature, awareness, and importance. It has matured over the years and has undergone a series of changes and improvements based on continuous

challenges at the interface of human and animal health and the need to assess and monitor the occurrence of antimicrobial resistance in bacteria from animals, foods, and humans.

The goals of the NARMS program are:

1. Provide descriptive data and trends on antimicrobial susceptibility/resistance patterns in zoonotic, food-borne bacterial pathogens, and select commensal organisms;

2. Respond to unusual or high levels of bacterial drug resistance in humans, animals, and retail meats in order to contain or mitigate resistance dissemination;

3. Design follow-up epidemiology or research studies to better understand the phenomenon of resistance; and

4. Assist the FDA in decision making for approving safe and effective drugs for humans and animals, as well as promote prudent and judicious use of antimicrobials.

General Considerations

In addition to its focus on the four questions listed in its charge, the Subcommittee also noted that a group of common themes emerged from its deliberations and review that warranted comment and consideration. These themes included: the need for an improved, statistically valid, and rigorous sampling strategy; timeliness of reports and reporting; harmonization of data among the three components of the program; and the creation of a contemporary surveillance platform that would enable the participants to conduct hypothesis-driven research, make inferences from a stronger statistical foundation, and add greater value for data utilization and the conversion of data into information to better support policies, regulations, and public health impact.

Our responses and findings to the four questions, in large part, address these recurring themes. The Subcommittee noted that there continues to be financial constraints for the NARMS program. Yet, when considering the increasing value of NARMS and the very favorable upside potential to accrue more benefits in the future, the Subcommittee is impressed with the current return on investment and would rank NARMS as a high priority and mission-critical function, especially for the Center for Veterinary Medicine (CVM)/FDA. In addition, the Subcommittee believes that creating a business plan may also be helpful for planning purposes and encourages the participants to also explore funding possibilities outside of the traditional federal budget process.

NARMS is considered a public health system with an emphasis on protecting human health; yet, the animal health benefits seem underappreciated. It is important that all three partners of NARMS accrue benefits as true partners. Veterinarians and animal health officials are also clients and would not be well served if their antimicrobial therapies become less effective due to a building resistance problem no matter what the cause.

Practicing veterinarians and producers are likely to make better decisions regarding prudent and therapeutic drug use if they were more knowledgeable about the level of resistance/susceptibility of pathogens to antimicrobial agents. In order to elucidate the risk factors for animal and human infection by antimicrobial-resistant pathogens and understand the true impact of antibiotic use, non-use and resistance to human health, animal health, trade, and environment, better data sharing is essential.

Although not a question posed to the Subcommittee, there were a number of public comments that were critical of the fact that actual drug usage data were not readily accessible or shared. This reality creates a significant limiting factor to the further analysis of NARMS data. The Subcommittee recognizes that there are confidentiality issues of concern; however, the Subcommittee also believes that this data gap represents a critical barrier for NARMS to achieve its objectives and further utility. The group encourages the industry to work with NARMS and to try to develop a confidential component of NARMS data that better links such data with true public health impact, yet does not compromise sensitive industry data.

***Question 1*: Are there inherent biases in the sampling strategies employed in NARMS? If so, how can they be improved to ensure that the data and our interpretations are scientifically sound given current resources?**

NARMS, as originally conceived, used bacterial strains being collected for other purposes for screening for antimicrobial resistance. It can be argued that at the time the program was initiated that this was an appropriate approach, reflecting uncertainties about what would be found, and the potential utility of the data. In the intervening 10 years, the value of the data has become increasingly obvious, with NARMS findings playing a key role in both epidemiologic studies and regulatory activities. This was underscored in the public meeting, where there was virtual unanimity among representatives from industry, consumer groups, and academia as to the importance of the system. Under these circumstances, there is a need to critically re-evaluate the sampling approach to assure that the data being generated can withstand scrutiny from both a scientific and regulatory perspective. The Subcommittee strongly believes that resistance data must be able to withstand legal and regulatory scrutiny and challenges. This underscores the importance of a careful review of the potential biases, especially in USDA isolates. Failure to do this will likely limit the long-term value of the NARMS findings. While appropriate sampling may initially cost more than using a convenience sample, it invariably results in long term savings, because poorly collected data do not have to be discarded, and questions can be answered efficiently with appropriately sized samples.

NARMS currently screens strains from three sources for antimicrobial resistance:

1. Human Component: This component draws from isolates submitted to state health department laboratories for testing and species confirmation. Since 2003, all 50 states have been forwarding a representative sample of non-typhi Salmonella,

Salmonella typhi, and *Escherichia coli* (*E. coli*) O157:H7, and 10 states (in FoodNet) have been participating in FoodNet surveillance.

Potential biases: Samples are collected as a proportion of all isolates submitted to the participating state health department laboratories. However, there are clear differences from state to state with regard to which isolates are received by the state health department laboratories. In many states, clinical laboratories are not required to submit all isolates (or any isolates) of a particular species; and, consequently, there may be striking differences among states and among regions of a single state (i.e., urban vs. rural) in relative number and source of isolates. Biases may also arise at the physician level: stool cultures may not be ordered until after a patient has failed conservative therapy (including, in many instances, an empiric course of ciprofloxacin). Finally, it must be recognized that this is a passive system: With the exception of FoodNet states, there is no effort to assure that isolates, even those whose submission may be required by law, are actually submitted.

Ideally, one would like to see a true national random sample of clinical isolates in each species of interest with comparable representation from all states and all regions within states. If the current sampling scheme is maintained, there must be some type of data stratification to provide data that accurately reflect national trends. There is also a need for some type of periodic active sampling of clinical labs, to assess the representativeness of the isolates being submitted through NARMS to the overall population of clinical enteric isolates. Neither of these approaches will address the issue of potential biases at the physician level: Targeted studies will also be needed to assess the actual significance of this potential bias.

There is definite value in assessing overall levels of antibiotic resistance among isolates that are part of the intestinal flora of healthy human populations. As an example, documentation of high population-based levels of resistance to vancomycin among enterococci from healthy adults in Europe provided a key data point in decisions to ban further use of avoparcin in animals. In this context, it should also be recognized that there is great fluidity in gene movement among bacterial species; and, consequently, presence of resistance genes in any species is of potential interest in understanding emergence of resistance in humans. Continued surveillance in this area should be strongly encouraged as part of the NARMS mission. However, while some samples for these types of studies have been taken from normal human volunteers, most appear to have come from patients for whom stool samples were submitted for other reasons. It must be recognized that samples from this latter group have definite biases, given that these patients will have had other medical conditions that have prompted samples to be collected.

2. The Retail Meat Component was launched in 2002 with isolates from retail meat collected by investigators in selected FoodNet sites. The methodology for the sampling has undergone subsequent revision, but the overall sample size remains very small, particularly if any type of stratification is done on the data.

Potential Biases: Samples are collected from a limited number of areas for a small number of products. While major trends may be observed, the small sample size and lack of a national sampling strategy make interpretation of these data difficult.

These are extremely important data, as they reflect sampling at one of the closest points to the "fork" in the farm-to-fork continuum. A statistically valid national sampling scheme may not be possible given the potential cost. In this setting, serious consideration should be given to limiting sampling to specific, hypothesis-driven studies designed to provide an understanding of sources and risk factors for antimicrobial resistance.

3. Animal Component: This component utilizes isolates from three primary sources: (a) The USDA in-plant Hazardous Analysis and Critical Control Point (HACCP) monitoring system; (b) clinical isolates submitted through diagnostic laboratories; and (c) isolates collected as part of the USDA-Animal Plant Health Inspection Service (APHIS) National Animal Health Monitoring System (NAHMS).

Potential biases: The USDA in-plant HACCP monitoring does not reflect a random sample of processing plants, a problem exacerbated by the fact that plants that are out of compliance have increased numbers of samples collected. At a minimum, sampling must be restricted to the first set of samples collected in a plant (i.e., exclusion of additional sampling sets from plants that are not in compliance). USDA should be encouraged to assess its current HACCP sampling strategy and to see if modifications in the sampling strategy can be made to make the sample more closely resemble a truly representative national sample. Alternatively, consideration should be given to an ongoing "baseline" sampling scheme to provide nationally representative data on levels of contamination of raw product at the time of slaughter.

NAHMS data represent a statistical approach to sampling on-farm populations. While potentially useful, these samples fail to provide a true national sample of on-farm isolates. As with the retail food study, on-farm data are essential in understanding movement of resistance through the farm-to-fork continuum. However, given the difficulties in obtaining truly representative national data at an on-farm level, it may be best to limit on-farm isolate collection to specific, hypothesis-driven research studies designed to identify sources and risk factors for acquisition of resistance.

Clinical diagnostic laboratory data have potentially the greatest biases, representing a completely non-random sample and a sample that comes from settings in which there is likely to have been antimicrobial use. These data have potential value as an "early warning system" for emergence of resistance in the setting of clinical use of specific antibiotics. However, these data should not be used in epidemiologic studies and clearly should not be combined with animal data from the other isolate sources noted above. These samples also represent the only attempt to characterize resistance/susceptibility of targeted pathogens recovered from companion animal populations and exotic pets, a growing concern for veterinary medicine and public health research.

The Subcommittee noted with interest the progress of three USDA agencies – APHIS, the Agricultural Research Service (ARS), and the Food Safety and Inspection Service (FSIS) – in implementing the Collaboration in Animal Health and Food Safety Epidemiology (CAHFSE) program. This program is designed to be both a food animal disease monitoring system and a bacteria monitoring system taking place on-farm and in-plants over time. A particular emphasis of CAHFSE is to address issues related to antimicrobial resistance. This joint effort could eventually help improve the understanding of the process of antimicrobial resistance and the link from the farm-to-table continuum. Questions about the true burden of illness and an attempt to quantify public health impact with the emergence of resistance remain elusive at best. The Subcommittee is also concerned about the issue of confidentiality of on-farm data and the ability to link human and animal data sets. Yet, overall, there is real merit in the further coordination and linkage of data from all components in a timely manner; thus, the Subcommittee strongly encourages further pilots like CAHFSE to achieve greater specificity in our understanding and the discovery of new critical associations from the various sampling and epidemiological projects and studies.

FINDINGS:

- For human samples, there is an inherent bias, because clinical laboratories and physicians select and handle samples differently from state to state. While a true random sample would be ideal, it may not be completely feasible; thus, the Subcommittee believes that stratifications of the current sampling system would be useful and could assist in the identification of national trends. Furthermore, the adoption of a more active and targeted sampling strategy would also improve the current strategy.

- There is value in assessing the level of antimicrobial resistance present in the intestinal flora of healthy individuals. While NARMS attempts to do this, further bias may occur because of how these samples are selected. Thus sampling from a population of truly healthy individuals would be beneficial.

- With regard to retail meat, the relatively small sample size and lack of national sampling strategy limits a broader interpretation and inference of data. It may be more useful to adjust this sampling strategy to help answer specific, hypothesis-driven questions and studies.

- For the animal component, sampling biases occur because the current system does not reflect a randomized strategy for selecting processing plants. It would be useful for the USDA to redesign its HACCP sampling strategy to become a truly nationally representative strategy.

- The use of data from USDA's National Animal Health Monitoring System and other on-farm data has real potential utility but is currently limited because it is not representative of a national sample. Therefore, the NARMS sampling strategy

may prove more useful if implemented based on specific hypothesis-driven research where risk factors for resistance would be the focus.

- Clinical diagnostic laboratories data are especially biased and should be limited to use as an early warning system for emerging resistance.

Question 2: **Are there epidemiological and/or microbiological research studies that would better serve the goals of NARMS and the regulatory work of FDA?**

Applied research is already a cornerstone of all three components of NARMS. This research can be grouped into three broad types or categories: the development and optimization of laboratory methods for susceptibility testing, strain characterization, and resistance determinant detection; use of NARMS isolates and data as platforms to achieve program goals; and pilot studies to explore new program opportunities and approaches. Examples of the first type include development of a Clinical and Laboratory Standards Institute (CLSI)/ National Committee on Clinical Laboratory Standards (NCCLS) approved broth microdilution method for Campylobacter susceptibility testing and development/adaptation of genotyping methods (e.g., Pulsed Field Gel Electrophoresis, Multilocus sequence typing) for Salmonella and Campylobacter. Examples of completed or existing platform studies include epidemiological and microbiological studies into the clinical consequences of multiple drug resistant (MDR) pathogens and the dissemination of resistant bacteria and genes. Finally, examples of the third type include the USDA-funded CAHFSE program, Iowa Retail Meat, and VetNet projects.

An active applied research program is critically important to the continued success of NARMS, and the Subcommittee believes that it is appropriate to continue research in these three broad categories with expansion into a fourth, which is targeted hypothesis-driven research. The progress already made in methods development should be expanded with increased emphasis on detection of resistance genes in fecal, carcass, and food samples, without regard to the species of bacteria in which they reside or whether they are from pathogens or commensals. Development of molecular methods for routine identification of resistance genes from field samples is an important long-term goal for the program. The apparent ease with which many of these genetic determinants spread among bacteria and ecological niches indicates that there should be a fundamental expansion of emphasis on the unit of analysis in monitoring and research from the organism level exclusively to both the organism and gene levels. Pilot studies are valuable testing grounds for new methods, approaches, and sampling plans, but they should be carefully planned and coordinated to ensure efficient use of resources.

There is also a need for more hypothesis-driven research to provide answers to some important public health questions related to the NARMS mandate, including the assessment of human health risks. This research should expand the NARMS research portfolio; and, ideally, it would enhance collaboration with scientists in academia and other sectors and be facilitated, or, in some cases, made possible by leveraged funding from outside sources, such as NIH. This would also be facilitated by improvements in

data management, linkage, and retrieval. In particular, this research should improve our understanding of the ecology of antimicrobial resistance, the flow of resistance genes and bacteria through the farm-to-fork continuum, and the resultant impact on human health. This could be pursued in a variety of ways, for example, by identifying one or more well-defined locales or catchment areas where it is feasible to collect antimicrobial use and resistance data that can be directly linked epidemiologically. This extends the concept of the pilot study to a large epidemiological study. A potential deficiency of this type of research, however, is that given the practical limitations in current sampling and laboratory techniques, it has limited capacity to measure some of the longer-term implications of resistance selection pressures in microbial populations, such as the dissemination of resistance genes among microbial ecosystems or co-selection by linkage of genetic determinants that may take years to develop in disparate parts of the country or in various animal or human ecosystems. Therefore, there still is a need for hypothesis-driven research that identifies associations between antimicrobial use and resistance across broad populations and regions (e.g., antimicrobial use and resistance at the national level in both animals and humans).

FINDINGS:

- The Subcommittee strongly believes that the NARMS program should further develop its research portfolio in the areas of: laboratory methods; platform development and studies in support of program goals; and pilot projects that enhance NARMS goals, utility, and approach.

- In addition, the Subcommittee encourages the program to expand its hypothesis-driven research, especially with a new focus on assessing human health risks. To do this effectively, the Subcommittee further encourages the NARMS Team to expand its research collaboration and partnerships in academia and with the NIH.

- The ecology of resistance is complex and dynamic, and hypothesis-driven research represents the next logical area of expansion. Understanding the flow of resistance genes and bacteria across the farm-to-fork continuum and the resultant human health impact is key to future prevention and intervention strategies, and, thus, a critical research focus for the NARMS program.

***Question 3*: Are our current plans for data harmonization and reporting appropriate? If not, what alternative approaches would you consider, and what should be the top priorities for harmonization and reporting?**

It is clear from all parties involved in NARMS, as well as public commentators, that there is a crucial need for a real-time integrated database that would allow access to all the components of the NARMS program (CVM, USDA [including FSIS, APHIS, ARS], and CDC) and the production of timely reports. Given the nature of microbiological data, as well as rapidly changing and emerging problems, timeliness to data access is essential. Great progress has been made in harmonizing microbiological techniques; the focus now must be on creating an easily accessible and searchable database.

To accomplish this, it is important that the participants define the attributes of a single database structure that would allow all data from all three NARMS components to be tabulated in a single database. The structure should be related to how data will be interpreted. All components should agree on data needs and linkages, as well as what is actually desired from the data. Considerations should be given to how the data will be used; that is, will they be for surveillance, monitoring, research, or regulatory use, and understanding any bias inherent in any of the sampling strategies. These attributes should then define the appropriate database architecture. This structure must be defined from the perspective of the data attributes and not the information technology resources needed to implement it.

This database should be a searchable and dynamic tool and not a series of flat portable document format (PDF) files. The Subcommittee foresees that this database would be populated real-time using modern web-based strategies with off-the-shelf software. For all three units, once data have been collected and validated according to local agency standards, the data should be routinely entered into the database. If all data elements are not available (e.g., pulse-field gel electrophoresis results), they can be entered as the data are generated. Milestones using tools such as Gantt charts should be defined to streamline data capture and timely entry into the database.

The various NARMS units can design their own software interfaces to access this central database depending on their individual needs for data analysis and available software support. This would still allow individual NARMS components to perform their own level of data analysis and summarization. Because of the confidential nature of some of these data, the integrated database should first be restricted to internal government use. This is a priority for both public health and regulatory needs. Should public access be desired in the future, a segregated database could be constructed where confidential data elements are restricted to government access and public data is released separately as data are generated.

The advantage of such a real-time integrated database is that report generation could also be real-time. The existing delay in producing executive reports would be significantly reduced. Report format would be a function of the unit's needs for analysis and not a function of database structure. A range of types of reports would be possible as no one product will fit all needs. Simple tabular presentations as presently produced may not be adequate for some groups/stakeholders. Such a tool would also facilitate the writing of scientific publications as well as mitigating outbreak characterizations. Rapid querying by NARMS personnel would be available as close as their desktop computers. Today's database technology is sufficiently portable and secure that the unique software/hardware environments exist so that each NARMS participant should be able to easily access a central database. This database should be maintained at a single site to ensure database and data security, and plans for maintenance should be built into the system. The sophistication of the database structure is not crucial; the uniform data structure capable of categorizing all three datasets is crucial. These data must be cross-linked by species, product, and microbiological descriptors, as well as data elements needed for proper interpretation.

The concept of database integration could also be carried a step further by attempting to start the collection of drug use data. One source is data that are mandated by existing regulations should be reported by manufacturers on gross drug sales. However, these data are not granular enough to correlate to the species or local farm level. In an ideal world where financial resources or bureaucratic divisions are not constrained, microbial data collection would be accompanied by metrics of drug exposure. Techniques such as existing multi-antimicrobial drug screening approaches used by FSIS and FDA for residue monitoring might be applied to select tissue samples collected for microbiology to confirm drug exposure. A pilot study could be employed to assess the feasibility of this approach.

Finally, the lag time between data collection and report generation is excessive and diminishes the utility of information. In summary, there is no excuse for the present situation where report generation lags some four years behind data collection. Data should be entered on a real-time basis. Public health and regulatory decision making requires real-time data. The Subcommittee envisions this process to start with internal government data sharing and then move to public data access of non-confidential elements. Should hard-copy reports still de desired by specific shareholders, such a system would facilitate both detailed analysis as well as timely publication.

FINDINGS:

- There is a critical need to create a real-time integrated database for all components of the NARMS program and the production of more timely reports.

- The use of the data and the data attributes should dictate the information technology solution. A web-based, real-time system is envisioned that would be flexible enough to allow separate data-entering, reporting, and handling potentially confidential data.

- The Subcommittee understands the need for accurate and responsive data that support improved decision making and regulatory analyses. However, the NARMS Team is encouraged to move toward a database that can be more readily shared with researchers and other users who could add further value to the data and conduct research or for further analyses. The Subcommittee further stressed the need to capture drug use and/or exposure data as part of this database.

- By improving the speed and quality of reports, the Subcommittee believes that the NARMS Team could then expand the utility of the information to include: pre-market approval planning; better linking of animal and public health communications; and expansion of utility and availability – both to other researchers who could add further value and utility for the NARMS program and eventually directly to the public.

***Question 4*: Are the current NARMS international activities adequate to maintain a significant collaboration with worldwide efforts to mitigate the spread of antimicrobial-resistant food-borne bacteria?**

International activities are critical, because antibiotic resistance is very much a global problem. Today, approximately15% of our food is imported with the likelihood that food imports will substantially grow, and these products will largely be coming from developing countries. Many imported foodstuffs, such as seafood and fresh fruits, are already imported in much higher percentages. Because of the rapidly expanding global food system, the Subcommittee envisions that increasing levels of collaboration must occur among countries and international health organizations worldwide.

As a global issue, antimicrobial resistance cannot be addressed by a single country's program. The complexity of the food system and global distribution of foods demonstrate the need for continued collaboration with other international antimicrobial resistance monitoring programs. It is also crucial that at the international level there is a single and unified consensus representing all the NARMS partners. There should be no confusion or differences in the interpretation of NARMS data.

In 2003, a NARMS report (NARMS-Enteric Bacteria 2003 Executive Report) recognized the potential health hazards of antimicrobial resistance. The World Health Organization (WHO), the Food and Agriculture Organization (FAO) of the United Nations, and the World Organisation for Animal Health (aka OIE) recommended that countries implement national monitoring programs for the use of antimicrobials in animals and the occurrence of antimicrobial resistance in bacteria from animals, foods of animal origin, and cases of human illness. Challenges have not changed with regard to usage of antimicrobials and the occurrence of resistance. The Subcommittee believes that there is a need to compare the usage of antimicrobials and the occurrence of resistance among countries; to integrate our knowledge of pathogens and trends; to identify targeted research themes; to continue the development of risk assessment models; and to continue the development of policies for containment.

Currently, all three "arms" of the NARMS program have international activities; yet, better coordination among the agencies should be an important goal. There seems to be no question that this is an important element of all three "arms," yet synergies among the separate programs must be reinforced.

The CVM has a multi-pronged approach that includes education/outreach, expanded participation in international activities, and increased research and surveillance programs. Although Pulse-Net, predominantly a CDC project, continues to expand globally, it requires further expansion done even more rapidly.

NARMS currently supports the efforts of various international organizations (e.g., Danish Integrated Antimicrobial Resistance Monitoring and Research Programme; Canadian Integrated Program for Antimicrobial Resistance Surveillance; ResistVet Project: The US-Mexico-Guatemala Antimicrobial Resistance Monitoring Program for Foodborne

Pathogens; and Global Salm-Surv (GSS)). NARMS and GSS have played an important confirmatory role with regard to antimicrobial resistance in the U.S. and other countries. This program should be provided continuing support and must be improved to include better surveillance. The Subcommittee encourages the continued cooperation and support of the WHO GSS through Institute Pasteur, the Danish Institute for Food and Veterinary Research, CDC, the Canadian Public Health Agency, CVM, the Animal Science Group of the Netherlands, OZ FoodNet Australia, and Enter-Net. Furthermore, ResistVet, a project between the U.S. and Mexico, should be nurtured and encouraged – eventually leading to an independent monitoring program in Mexico.

It is time for international partners that collaborate in surveillance programs to develop stronger and more robust programs for monitoring public health issues within participating countries. WHO has endorsed a tripartite approach to include isolates from human clinical cases, food animal and retail meats, and superficially conducting antimicrobial resistance and monitoring food-borne pathogens. Such an approach should continue to be endorsed by the NARMS Consortium.

Scientist training, particularly microbiologists involved in international antibiotic resistant programs, should be encouraged and supported. Continuing education and training are essential for the creation and implementation of quality programs. International workshops devoted to embracing the quality of data collection and uniform reports pertaining to surveillance are growing in importance.

Globalized trade has accentuated the importance of international cooperation in training, surveillance, and in monitoring and controlling microbial outbreaks. Such globalization has also brought about the importance of recognizing emerging zoonotic diseases – again a need for international cooperation and communication. As a result of this globalization, a number of important international collaborations have evolved, including the International Network of Integrated Surveillance for Antimicrobial Resistance in Enteric Bacteria (INISAR). It is imperative, particularly in a global economy and one in which the U.S. is a major stakeholder, that international ties and collaboration should continue and be strengthened.

FINDINGS:

- Antimicrobial resistance is a global issue and cannot be completely understood or addressed by individual national programs; thus, the current NARMS international activities must be continued and expanded, especially as imported food supplies to the U.S. are increased.

- There is a further need to improve coordination among international animal and human health organizations with regard to antimicrobial resistance. The work of the NARMS Team, along with a handful of similar global activities, should help provide an international leadership forum and serve as both a critical mass to expand activities and a model for other countries and organizations to emulate.

- Internationally, NARMS or NARMS-like programs must recognize the continuing need to adopt advanced technologies, the importance of quality data collection, and timely reporting in recognition of emerging public health issues.

- The Subcommittee endorses the idea that there should be a single U.S. NARMS position, a single entity or spokesperson to represent NARMS in global settings, and a standardization of messaging and reporting.

- The NARMS Team currently assists in international training, and the Subcommittee encourages the continuation and expansion of this important role.

Summary

The NARMS subcommittee was impressed with the genuine commitment and dedication of the NARMS participants and with the collegial and constructive presentations and remarks from the public. The NARMS program has made outstanding progress over the last decade and has gained the respect and acceptance of a diverse public, including pharmaceutical companies. The evolution and maturation of NARMS since its inception in 1996 has been steady and has been characterized by continuous learning and improvement. There are clearly a number of existing activities that are going well and deserve to be continued. Yet, the Subcommittee also found several critical areas of need that were disclosed in its evaluation of the four questions posed to the group and have been listed in the Subcommittee findings. The Subcommittee believes that the NARMS participants are now in a better position to build on the current good will and program strengths that may not have existed in the past. Therefore, the NARMS Team should not just consider how the program can continue to meet its current objectives but should now consider and explore new opportunities not envisioned a decade ago.

There is nothing on the horizon to suggest that the progressive complexity and interdependence of animal agriculture, global food systems, and public health will change or slow down. On the contrary, these integrated systems continue to expand in scope, scale, and potential consequences. Therefore, in addition to responding to specific findings, the Subcommittee encourages the NARMS Team to step back from just considering incremental changes and improvements and to now reconsider the program's current objectives in light of the extraordinary and unprecedented changes in agriculture, industry, foods, and the contemporary challenges to public health. The Subcommittee believes that NARMS data should become more predictive, responsive, and expansive, including the addition of pre-market product approval, global and better linked through wider stakeholder involvement to animal and public health communities.

The Subcommittee encourages the development of a 10-year NARMS plan and consideration of beginning a new phase of program development. It is a propitious time for the NARMS Team to implement a visioning process, develop a concurrent business plan, and create an expanded opportunity horizon to improve public and animal health in this new era. The NARMS program has performed well when one considers its genesis, convenience-sampling strategy, limited resources, and relatively differing agency cultures. However, these legacy and founding principles no longer fit the growing importance of the program or the growing societal and public health need.

Acknowledgements

The Subcommittee expresses its appreciation to the members of the NARMS Team who made presentations; to public presenters and those submitting comments; and to FDA staff, including Dr. Carlos Peña and Ms. Joanne Kla, who capably supported the planning and logistics for the Subcommittee meeting. These collective efforts were invaluable to our Subcommittee and to the completion of this report.

Appendix 1: Subcommittee Members and Participants

Larry M. Granger, DVM, is currently the Director of the Centers for Epidemiology and Animal Health (CEAH), part of the United States Department of Agriculture's Animal and Plant Health Inspection Service, Veterinary Services. Dr. Granger earned his degree in Veterinary Medicine in 1979 from Michigan State University. He was in private practice for nine years before joining the Michigan Department of Agriculture as the Pseudorabies Eradication Program Manager. He stayed with the Michigan Department of Agriculture and held several different positions before becoming Veterinary Services' Associate Deputy Administrator for Emergency Management in 2003, a position he held until he became the Director of CEAH, in 2006.

Susan K. Harlander, PhD, Senior Vice President Government and Industry Relations, BT Safety LLC. Dr. Harlander has more than 20 years experience in the food industry, with nine of those years in senior research and development management positions where she was involved in several trace recall incidents involving dairy and processed food products. She has served on numerous dairy and food industry trade association committees, including the Grocery Manufacturers of America, National Food Processors Association, and the International Dairy Foods Association to name a few. Dr. Harlander serves as a consultant to farm organizations, grain processors, food manufacturing companies, trade associations, and biotechnology providers, and has been active in domestic and international issues related to traceability and identity preservation of genetically modified foods. While an Associate Professor in the Department of Food Science and Nutrition at the University of Minnesota, Dr. Harlander served on numerous Scientific Advisory Boards for food companies and spent summers working for companies like General Mills and Procor Technologies. She was the principal investigator on numerous grants and has published over 110 referred papers, book chapters, and monographs and has made over 400 presentations to scientific and lay audiences. She has served on FDA's Science Board; FDA's Food Advisory Committee; USDA's National Agricultural Research, Education, Extension and Economics Advisory Board; and the NRC's Board on Agriculture and Food Chemicals Codex Committees. As a former Associate Professor of Food Microbiology and Biotechnology, Dr. Harlander brings extensive experience in food microbiology and an understanding of biological and chemical agents that could be used in food bioterrorism, as well as naturally occurring pathogens that contaminate the food supply.

Lonnie King, DVM, Director, National Center for Zoonotic, Vector-Borne, and Enteric Diseases, CDC, received his Bachelor of Science and Doctor of Veterinary Medicine degrees from The Ohio State University in 1966 and 1970, respectively. He earned his Master of Science degree in epidemiology from the University of Minnesota while on special assignment with the U.S. Department of Agriculture in 1980. He also received his Master's degree in public administration from American University in Washington, DC, in 1991. Dr. King is a board-certified member of the American College of Veterinary Preventive Medicine and has completed the Senior Executive Fellowship Program at Harvard University. He has served as president of the Association of American

Veterinary Medical Colleges from 1999-2000 and was vice chair for the National Commission on Veterinary Economic Issues from 2000-2004. Dr. King also has served as administrator for the Animal and Plant Health Inspection Service, U.S. Department of Agriculture. He recently completed his tenth year as dean of the College of Veterinary Medicine, Michigan State University, and has assumed the position of Director of the National Center for Zoonotic, Vector-Borne, and Enteric Diseases at the Centers for Disease Control and Prevention in Atlanta. Dr. King is a member of the National Academies of Science through his election into the Institute of Medicine, is on the Scientific Advisory Board for the FDA, and is a member of the newly formed Pew Commission Studying Animal Agriculture and Public Health.

Scott A. McEwen DVM DVSc, Diplomate ACVP, is a Professor, Department of Population Medicine, University of Guelph, Guelph, Ontario, Canada. Dr. McEwen obtained his DVM and Doctor of Veterinary Science degrees from the University of Guelph. His research focuses on the epidemiology of foodborne infections in food animal populations, particularly *E. coli* and antibiotic resistant organisms, but also Salmonella and other pathogens. He has extensive experience in conducting epidemiological studies in cattle, swine, and other food animal species and has also participated in a number of studies of zoonotic infections in humans, including *E. coli* O157:H7 and antimicrobial resistance in commensals. His research on *E. coli* O157:H7 and related organisms focuses on the distribution of fecal shedding in cattle and risk factors for infection in cattle and humans. He and his co-workers are also active in simulation modeling of potential intervention strategies (including vaccination) for this infection on farm and throughout the food chain. His research program in antimicrobial resistance focuses on the determinants of selection and assessment of human health risks.

Since 1986 he has taught food safety to veterinary students and graduate students in a variety of degree programs and has been the principal research advisor of over 25 MSc and PhD students. He is author or co-author of over 100 publications in referred scientific journals and has delivered invited research presentations in nine countries.

He consults on food safety, antibiotic resistance, epidemiology, and other veterinary public health matters with a number of governmental and non-governmental organizations in North America and Europe, notably various food animal industry groups, the Alliance for the Prudent Use of Antibiotics, the World Health Organization, the United States Food and Drug Administration, and Health Canada.

He recently chaired Health Canada's Advisory Committee on Animal Uses of Antimicrobials and Impact on Resistance and Human Health, the World Health Organization's evaluation of the termination of the use of antimicrobial growth promoters in Denmark, the FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Scientific Assessment, and an Expert Advisory Panel to a Judicial Review of Meat Inspection in Ontario.

J. Glenn Morris, Jr., MD, MPH&TM is Professor and Chairman of the Department of Epidemiology and Preventive Medicine at the University of Maryland School of Medicine and interim Dean of the University of Maryland, Baltimore, School of Public Health. He received his MD degree and a master's degree in public health and tropical medicine from Tulane University, New Orleans. He served as an Epidemic Intelligence Service Officer in the Division of Enteric Diseases at the then Centers for Disease Control in Atlanta from 1979-81. He is board-certified in both internal medicine and infectious diseases. Dr. Morris has authored over 60 textbook chapters and symposium proceedings and over 170 articles in peer-reviewed journals. He has had continuous federal grant funding since 1984; his scholarly contributions were recognized by election to the American Society for Clinical Investigation in 1996. He has served on four National Academy of Sciences expert committees dealing with food safety. From 1994-1996, he worked with the Food Safety Inspection Service, U.S. Department of Agriculture, on the preparation of the Pathogen Reduction/HACCP regulations. In 2005, he was awarded the James D. Bruce Memorial Award for Distinguished Contributions in Preventive Medicine by the American College of Physicians. Dr. Morris continues to have a strong research interest in the area of emerging pathogens: he maintains an active, NIH-funded laboratory working in the area of molecular genetics and molecular epidemiology; is involved in hospital studies looking at emergence of resistant microorganisms; has worked extensively with clinical, laboratory, and environmental issues related to harmful algal blooms; and serves as co-PI of the CDC Emerging Infections Program sentinel surveillance site (FoodNet) in Maryland.

Jim E. Riviere, DVM, PhD, is the Burroughs Wellcome Fund Distinguished Professor of Pharmacology; Director, Center for Chemical Toxicology Research and Pharmacokinetics, College of Veterinary Medicine; and Director of the Biomathematics Program of the College of Physical and Mathematical Sciences, North Carolina State University (NCSU), in Raleigh, NC. He is an elected member of the Institute of Medicine of the National Academies, serves on its Food and Nutrition Board, and is a fellow of the Academy of Toxicological Sciences. Dr. Riviere received his BS (*summa cum laude*) and MS degrees from Boston College and his DVM and PhD in pharmacology from Purdue University. He is a member of Phi Beta Kappa, Phi Zeta, and Sigma Xi, and has served on the Science Board of the Food and Drug Administration. His honors include the 1999 O. Max Gardner Award from the Consolidated University of North Carolina, the 1991 Ebert Prize from the American Pharmaceutical Association, the Harvey W. Wiley Medal and FDA Commissioner's Special Citation, and the Lifetime Achievement Award from the European Association of Veterinary Pharmacology and Toxicology. He is the Editor of the Journal of Veterinary Pharmacology and Therapeutics and co-founder and co-director of the USDA Food Animal Residue Avoidance Databank (FARAD) program. He has served as an officer in various Specialty Sections of the Society of Toxicology, and has served on the Editorial Boards of various toxicology, pharmacology and veterinary journals. He has published over 400 full-length research papers and chapters, holds five U.S. Patents, and has authored/edited 10 books in pharmacokinetics, toxicology, and food safety. His current research interests relate to applying biomathematics to problems in toxicology, including the risk assessment of chemical mixtures, pharmacokinetics,

absorption of drugs and chemicals across skin, and the food safety and pharmacokinetics of tissue residues in food producing animals.

John A. Thomas, PhD, was born and educated in the Midwest. He received his undergraduate degree at the University of Wisconsin and his MA and PhD degrees at the University of Iowa. He has held professorships in departments of pharmacology and toxicology in several medical schools including Iowa, Virginia, and West Virginia. Professor Thomas has been the mentor for many doctoral students and has trained several postdoctorals. From 1973 to 1982 he served as Associate Dean of the School of Medicine at West Virginia University where his responsibilities included graduate programs and research. In 1982, Dr. Thomas moved into the healthcare industry where he became Vice President for Corporate Research at Baxter Healthcare. While in industry, he was involved in new drug development, including recombinant DNA-derived therapeutic agents. Dr. Thomas served as Vice President at the University of Texas Health Science Center at San Antonio from 1988-1998. He is the author of more than a dozen textbooks and research monographs and has published nearly 400 scientific articles in the area of endocrine pharmacology and reproductive toxicology. He is a member of numerous societies, including the Endocrine Society, the Teratology Society, American Society for Pharmacology and Experimental Therapeutics, Society of Toxicology, and the American College of Toxicology. Professor Thomas serves on several editorial boards of biomedical journals and has been a member of the National Library of Medicine Literature Selection Technical Review Committee. Dr. Thomas served as a Specialty Editor for Toxicology and Applied Pharmacology and is on the Editorial Board of Food and Chemical Toxicology. He served as member on the Air Force Science Advisory Board. He has been a member of the Institute of Medicine/National Academy of Science Committee on Micronutrients, and he is past-Chairman of the Expert Advisory Committee of the Canadian Network of Toxicology Centers. He is a member of the FDA Science Advisory Board. Recently, Dr. Thomas served as Chairman of the NTP/NIEHS, Center for Evaluation of Risk to Human Reproduction, Expert Panel on Ethylene and Propylene Glycol as well as being a member of the Expert Panel on soy infant formula and genistein. He is a Diplomate and Fellow in the Academy of Toxicological Sciences as well as a Fellow in the American College of Toxicology. He continues to serve on many scientific boards and committees in the chemical and pharmaceutical industry. He served as Vice President for the Texas Society for Biomedical Research, as a member of the Board of Trustees of the International Life Sciences Institute and on the Board of Directors of the Academy of Toxicological Sciences. Dr. Thomas is Past-President of the Academy of Toxicological Sciences. He was named the 1999 recipient of the Distinguished Service Award from the American College of Toxicology. Dr. Thomas is Past-President of the American College of Toxicology. He is the recipient of several national awards, including the Merit Award from the Society of Toxicology, Certificate of Scientific Service (U.S.E.P.A.), Distinguished Lecturer in Medical Sciences (A.M.A.), Distinguished Service Award from the Texas Society for Biomedical Research and holds Distinguished Alumni Awards from both the University of Wisconsin and the University of Iowa. Recently, he was awarded an FDA Commissioner's Special Citation. He is an elected foreign member and Fellow of the Russian Academy of Medical Sciences.

Appendix 2: NARMS Presenters from Federal Agencies

Tom Chiller, MD, MPH, Past Chief of NARMS; Mycotic Diseases Branch; Division of Foodborne, Bacterial, and Mycotic Diseases; National Center for Zoonotic, Vector-Borne, and Enteric Diseases, CDC

Paula J. Fedorka Cray, PhD, Antimicrobial Resistance Research Unit, USDA

Patrick F. McDermott, PhD, NARMS Retail Meats, Center for Veterinary Medicine, FDA

David G. White, PhD, NARMS, Center for Veterinary Medicine, FDA

Appendix 3: Public Presenters

Richard A. Carnevale, VMD, Animal Health Institute

Michael Feldgarden, PhD, Alliance for the Prudent Use of Antibiotics

Steven Larsen, PhD, National Pork Board

Steven Roach, Food Animal Concerns Trust

Hua Wang, PhD, The Ohio State University

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 8, 2008, the comment period for the draft guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval," published in the **Federal Register** of October 15, 2007 (72 FR 58312). The draft guidance informed industry of FDA's current thinking regarding appropriate clinical study designs to evaluate antibacterial drugs, and asked sponsors to amend ongoing or completed studies accordingly. FDA is taking this action in response to a request for an extension of the comment period to allow interested persons additional time to review the draft guidance and submit comments.

DATES: Submit written or electronic comments by February 8, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Edward Cox, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6412, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 15, 2007 (72 FR 58312), FDA published a notice announcing the availability of a draft guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval." The purpose of the guidance is to inform industry of FDA's current thinking regarding appropriate clinical study designs to evaluate antibacterial drugs, and to ask sponsors to amend ongoing or completed studies accordingly. The guidance is in response to a number of public discussions in recent years regarding the use of active-controlled studies designed to show noninferiority as a basis for approval of antibacterial drug products. Some of these discussions have focused on specific diseases such as acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. These public discussions have contributed to FDA's evolving understanding of the science of clinical trials and, in particular, the appropriate role of active-controlled studies designed to show noninferiority in the development of antibacterial drug products.

The draft guidance recommends that sponsors provide justification for the treatment effect size and the proposed noninferiority margin for all antibacterial development programs for which approval will rely on noninferiority studies. The initial comment period for this guidance closed on December 14, 2007.

II. Reopening of Comment Period

On November 13, 2007, the Pharmaceutical Research and Manufacturers of America requested an extension beyond the December 14, 2007, deadline for the submission of comments. FDA recognizes the effect this guidance may have on the development of new antimicrobial products and that additional time may be needed for comment. Therefore, FDA has decided to reopen the comment period on the draft guidance until February 8, 2008, to allow the public more time to review and comment on its contents.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htmor http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–25601 Filed 1–3–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0489]

Request for Comments on the Science and Technology Report; Establishment of Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: On March 31, 2006, the Food and Drug Administration (FDA) charged the Science Board to evaluate FDA's science-based capacities to meet current and future public health challenges. The Science Board established a subcommittee on science and technology to perform the review and draft a report of findings and preliminary recommendations. The subcommittee report was presented and discussed at the December 3, 2007, Science Board Advisory Committee meeting, at which time the Science Board decided to obtain comments from the public on the subcommittee report. FDA is soliciting public comment on the subcommittee report on behalf of the Science Board.

DATES: To be considered, written or electronic comments on the subcommittee report must be received on or before February 4, 2008. All comments received while the docket is open will be forwarded to the Science Board for their review.

ADDRESSES: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments*. Select Docket No. 2007N–0489, "FDA Report on Science and Technology" and follow prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of

business on (see **DATES**). All comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be posted without change, including any personal information provided. All comments received while the docket is open will be forwarded to the Science Board for their review. All comments will also be discussed at the next Science Board Advisory Committee meeting. A notice of the next Science Board Advisory Committee meeting will be published at a later date. See **SUPPLEMENTARY INFORMATION** section for elctronic access.

FOR FURTHER INFORMATION CONTACT: Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF–33), 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, FAX: 301–827–3340, e-mail: *carlos.Peña,@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 31, 2006, FDA charged the Science Board to conduct a broad review of FDA scientific capacities, processes, and infrastructure which support FDA's core regulatory functions including the following: (1) Premarket review and consultation during the development of new FDA-regulated products; (2) oversight of marketed product quality; and (3) postmarket product safety surveillance and risk management. The following is the Commissioner of Food and Drugs' charge to the Science Board: "Review and report the broad categories of scientific and technologic capacities that FDA needs to fully support its core regulatory functions and decisionmaking throughout the product life-cycle, today and over the next decade." Specifically:

(1) Are there any important gaps in current scientific capacities in which FDA should substantially increase efforts, to ensure that it can address current or expected scientific demands of FDA's regulatory mission? In what areas should the agency maintain or strengthen its current level of work and capacity?

(2) Are there areas of science in which the agency should consider refocusing its efforts in order to better address current or anticipated future scientific demands of FDA's regulatory mission?

(3) What opportunities exist to enhance the overall effectiveness of FDA's scientific and tecbnologic capacity through coordination of scientific activities and priority setting across FDA components?

(4) What opportunities exist to better leverage FDA's scientific capacity through collaboration with other public agencies and private organizations? Are there other approaches to resource leveraging that FDA could pursue to better support needed scientific capacities?

The review was initiated to obtain advice regarding current science-based capacities and the degree to which they can prepare FDA for anticipated changes in science, technology and population health needs.

To respond to this request from the agency, the Science Board established a subcommittee on science and technology to perform the review. The subcommittee was supported by 30 outside experts, who were drawn from government, academia, and industry. Their efforts culminated in a subcommittee report of findings and preliminary recommendations. The subcommittee report was presented and discussed at the December 3, 2007, Science Board Advisory Committee meeting, at which time the Science Board decided to obtain comments from the public on the subcommittee report (an electronic copy of the subcommittee report is available at *http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007–4329b_02_00_index.html*).

II. Request for Comments

In accordance with 21 CFR 14.35, FDA is soliciting public comment on the subcommittee report, on behalf of the Science Board. Comments received while the docket is open will be forwarded to the Science Board for their review. Comments will also be discussed at the next Science Board Advisory Committee meeting. A notice of the next Science Board Advisory Committee meeting will be published in the **Federal Register** at a later date.

III. Submission of Comments

To help facilitate the public comment process upon the subcommittee report, FDA has established a public docket, on behalf of the Science Board. All comments submitted to the public docket are public information and may be posted to the FDA's Web site at: *http://www.fda.gov* for public viewing. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: December 28, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–25607 Filed 1–3–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Sickle Cell Disease Treatment Demonstration Program (SCDTDP), Health Resources and Services Administration (HRSA): NEW

In 2004 Congress enacted and the President signed into law Pub. L. 108–

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 8, 2008, the comment period for the draft guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval," published in the **Federal Register** of October 15, 2007 (72 FR 58312). The draft guidance informed industry of FDA's current thinking regarding appropriate clinical study designs to evaluate antibacterial drugs, and asked sponsors to amend ongoing or completed studies accordingly. FDA is taking this action in response to a request for an extension of the comment period to allow interested persons additional time to review the draft guidence and submit comments.

DATES: Submit written or electronic comments by February 8, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Edward Cox, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave.,Bldg. 22, rm. 6412, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 15, 2007 (72 FR 58312), FDA published a notice announcing the availebility of a draft guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval." The purpose of the guidance is to inform industry of FDA's current thinking regarding appropriate clinical study designs to evaluate antibacterial drugs, and to ask sponsors to amend ongoing or completed studies accordingly. The guidance is in response to a number of public discussions in recent years regarding the use of active-controlled studies designed to show noninferiority as a basis for approval of antibacterial drug products. Some of these discussions have focused on specific diseases such as acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. These public discussions have contributed to FDA's evolving understanding of the science of clinical trials and, in particular, the appropriate role of active-controlled studies designed to show noninferiority in the development of antibacterial drug products.

The draft guidance recommends that sponsors provide justification for the treatment effect size and the proposed noninferiority margin for all antibacterial development programs for which approval will rely on noninferiority studies. The initial comment period for this guidance closed on December 14, 2007.

II. Reopening of Comment Period

On November 13, 2007, the Pharmaceutical Research and Manufacturers of America requested an extension beyond the December 14, 2007, deadline for the submission of comments. FDA recognizes the effect this guidance may have on the development of new antimicrobial products and that additional time may be needed for comment. Therefore, FDA has decided to reopen the comment period on the draft guidance until February 8, 2008, to allow the public more time to review and comment on its contents.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to or two paper copies of any mailed comments, except that individuals may submit one peper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htmor http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–25601 Filed 1–3–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0489]

Request for Comments on the Science and Technology Report; Establishment of Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: On March 31, 2006, the Food and Drug Administration (FDA) charged the Science Board to evaluate FDA's science-based capacities to meet current and future public health challenges. The Science Board established a subcommittee on science and technology to perform the review and draft a report of findings and preliminary recommendations. The subcommittee report was presented and discussed at the December 3, 2007, Science Board Advisory Committee meeting, at which time the Science Board decided to obtain comments from the public on the subcommittee report. FDA is soliciting public comment on the subcommittee report on behalf of the Science Board.

DATES: To be considered, written or electronic comments on the subcommittee report must be received on or before February 4, 2008. All comments received while the docket is open will be forwarded to the Science Board for their review.

ADDRESSES: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments*. Select Docket No. 2007N–0489, "FDA Report on Science and Technology" and follow prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of

business on (see **DATES**). All comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be posted without change, including any personal information provided. All comments received while the docket is open will be forwarded to the Science Board for their review. All comments will also be discussed at the next Science Board Advisory Committee meeting. A notice of the next Science Board Advisory Committee meeting will be published at a later date. See **SUPPLEMENTARY INFORMATION** section for elctronic access.

FOR FURTHER INFORMATION CONTACT: Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF–33), 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, FAX: 301–827–3340, e-mail: *carlos.Peña,@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 31, 2006, FDA charged the Science Board to conduct a broad review of FDA scientific capacities, processes, and infrastructure which support FDA's core regulatory functions including the following: (1) Premarket review and consultation during the development of new FDA-regulated products; (2) oversight of marketed product quality; and (3) postmarket product safety surveillance and risk management. The following is the Commissioner of Food and Drugs' charge to the Science Board: "Review and report the broad categories of scientific and technologic capacities that FDA needs to fully support its core regulatory functions and decisionmaking throughout the product life-cycle, today and over the next decade." Specifically:

(1) Are there any important gaps in current scientific capacities in which FDA should substantially increase efforts, to ensure that it can address current or expected scientific demands of FDA's regulatory mission? In what areas should the agency maintain or strengthen its current level of work and capacity?

(2) Are there areas of science in which the agency should consider refocusing its efforts in order to better address current or anticipated future scientific demands of FDA's regulatory mission?

(3) What opportunities exist to enhance the overall effectiveness of FDA's scientific and technologic capacity through coordination of scientific activities and priority setting across FDA components?

(4) What opportunities exist to better leverage FDA's scientific capacity through collaboration with other public agencies and private organizations? Are there other approaches to resource leveraging that FDA could pursue to better support needed scientific capacities?

The review was initiated to obtain advice regarding current science-based capacities and the degree to which they can prepare FDA for anticipated changes in science, technology and population health needs.

To respond to this request from the agency, the Science Board established a subcommittee on science and technology to perform the review. The subcommittee was supported by 30 outside experts, who were drawn from government, academia, and industry. Their efforts culminated in a subcommittee report of findings and preliminary recommendations. The subcommittee report was presented and discussed at the December 3, 2007, Science Board Advisory Committee meeting, at which time the Science Board decided to obtain comments from the public on the subcommittee report (an electronic copy of the subcommittee report is available at *http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html*).

II. Request for Comments

In accordance with 21 CFR 14.35, FDA is soliciting public comment on the subcommittee report, on behalf of the Science Board. Comments received while the docket is open will be forwarded to the Science Board for their review. Comments will also be discussed at the next Science Board Advisory Committee meeting. A notice of the next Science Board Advisory Committee meeting will be published in the **Federal Register** at a later date.

III. Submission of Comments

To help facilitate the public comment process upon the subcommittee report, FDA has establisbed a public docket, on behalf of the Science Board. All comments submitted to the public docket are public information and may be posted to the FDA's Web site at: *http://www.fda.gov* for public viewing. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: December 28, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–25607 Filed 1–3–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Sickle Cell Disease Treatment Demonstration Program (SCDTDP), Health Resources and Services Administration (HRSA): NEW

In 2004 Congress enacted and the President signed into law Pub. L. 108–

Charter

Science Board to the Food and Drug Administration

Purpose:
The Secretary and, by delegation, the Assistant Secretary for the office of Public Health and Science and the Commissioner of Food and Drugs are charged with the administration of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and various provisions of the Public Health Service Act. The Science Board advises the Commissioner in discharging responsibilities as they relate to addressing specific and technically complex scientific issues of regulatory importance to FDA. The Board consists of a group of senior scientists with exceptionally accomplished backgrounds in evolving areas of new scientific research which will provide advice and further interaction between FDA, industry, academia, and other government agencies on technically complicated issues of regulatory importance.

Authority:
15 USC 1451 et seq . ; 21 USC 321, 341, 342, 343, 343-1, 344, 345, 346, 348, 349, 350, 350a, 351, 352, 353 (f), 355, 360b, 360c-j, 371, 375, 376, 378, 379e, 381, 393, 394, 881(b), 42 USC 217a, 241, 242, 242a, 262, 264 ; 21 CFR Part 14, 330 .10(a) ; the Board is governed by the provisions of Public Law 92-463, as amended (5 USC App .2), which sets forth standards for the formation and use of advisory committees.

Function:
The Board shall provide advice primarily to the Commissioner and other appropriate officials on specific complex and technical issues as well as, emerging issues within the scientific community, in industry, and academia. Additionally, the Board will provide advice to the Agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of Agency sponsored intramural and extramural scientific research programs.

Structure:
The Board shall consist of a core of 12 members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of chemistry, pharmacology, toxicology, clinical research, and other scientific disciplines. Members shall represent academia and industry. The Board may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Board may also include technically qualified federal members.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA Advisory Committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Board (when additional voting members are added to the Board to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

Members shall be invited to serve for overlapping four-year terms. Terms of more than two years are contingent upon the renewal of the Board by appropriate action prior to its expiration.

Temporary subcommittees consisting of two or more Board members may be established as needed to address specific issues within their respective areas of expertise. Subcommittees make preliminary recommendations regarding specific issues for subsequent action by the full Board. The Department Committee Management Officer shall be notified upon establishment of each subcommittee, and shall be provided information on its name, membership, function, and estimated frequency of meetings.

Management and support services shall be provided by the Executive Secretary of the Board located in the Office of Science and Health Coordination in the Office of the Commissioner, Food and Drug Administration.

Meetings:
Meetings shall be held approximately two times a year at the call of the Chair with the advance approval of a Government official, who shall also approve the agenda. A Government official shall be present at all meetings.

Because of the size of the Board and the variety in the types of issues that it will consider, FDA may, in

connection with a particular Board meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

Meetings shall be open to the public except as may be determined otherwise by the Commissioner or designee. Notice of all meetings shall be given to the public.

Meetings shall be conducted and records of the proceedings kept as required by applicable laws and Departmental regulations.

Compensation:
Members who are not full-time Federal employees shall be paid at the rate of the General Schedule 15, step 10, per day for time spent at meetings plus per diem and travel expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate:
The estimated annual cost for operating the Board, including compensation and travel expenses for members but excluding staff support, is $38,500.00. The estimated person years of staff support are 0.5 FTE, at an estimated annual cost of $56,599.00.

Reports:
In the event that a portion of a meeting is closed to the public, a report shall be prepared not later than November 1 of each year which contains as the minimum the function of the Board, a list of members and their business addresses, the dates and places of meetings, and a summary of the Board's activities and recommendations during the preceding year. A copy of the report shall be provided to the Department Committee Management Officer.

Termination Date:
Unless renewed by appropriate action prior to its expiration, the Science Board to the Food and Drug Administration will terminate on June 26, 2008.

Approved:

Date: June 26, 2006

Randall Lutter, Ph.D.
Associate Commissioner
for Policy and Planning, FDA

Order Code RL34334

CRS Report for Congress

The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007

January 24, 2008

Judith A. Johnson, Coordinator
Donna V. Porter, Susan Thaul, and Erin D. Williams
Domestic Social Policy Division

Prepared for Members and
Committees of Congress

The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007

Summary

Considerable attention has been focused on the ability of the Food and Drug Administration (FDA) to accomplish its mission with the funds provided by congressional appropriations and user fees. FDA regulates a wide range of products valued at more than $1 trillion of the U.S. economy. The agency plays a key public health role. FDA is responsible for the *safety* of most foods (human and animal) and cosmetics, and it regulates both the *safety* and the *effectiveness* of human drugs, biologics (e.g., vaccines), medical devices, and animal drugs.

In congressional hearing testimony and at other public venues, former FDA Commissioners, interest group representatives, and former high-ranking individuals in the agency or in the Department of Health and Human Services have argued that FDA is underfunded and at risk of being unable to fulfill all the statutory responsibilities assigned by Congress. Reports by the Institute of Medicine, the Government Accountability Office, and the FDA Science Board have made similar observations. The main voices in support of FDA budget levels, past and present, have been representatives of the various presidential administrations. Calls for cutting the FDA budget or maintaining it at the current level come from organizations, such as CATO and the Hoover Institute, that propose limitations on the agency's authority and, therefore, its need for funding. Some agency critics have expressed concerns about inefficiencies within FDA and its ability to manage its resources.

In order to inform the ongoing discussion about FDA, this report presents FDA's appropriations history and traces the evolution of the agency's statutory responsibility. It first provides a 28-year budget history for the agency along with personnel levels as shown by the number of full-time equivalent employees (FTEs). This report found that direct congressional inflation-adjusted appropriations (budget authority) to FDA almost doubled, and that the contribution of other funds, mostly user fees, increased more than 10-fold, resulting in an overall budget in FY2006 almost 2½ times that in FY1980. The agency's FTE level increased 19% overall, from a less than 1% increase in budget authority-funded FTEs and an almost fourfold increase in FTEs funded by other sources (mostly user fees).

The report also provides a more detailed examination of the budget and personnel levels for each of FDA's major activity areas: Foods, Human Drugs, Biologics, Animal Drugs and Feeds, and Devices and Radiological Health. Findings include the relationship of user fees to budget authority, declining funding of research, and summaries of the major laws enacted since FY1980.

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The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007

Introduction

There is growing debate about whether the Food and Drug Administration (FDA) has the ability to accomplish its mission with the resources provided by congressional appropriations and industry user fees. FDA plays a central role in protecting the public health in the United States, by regulating most of the food supply and vitally important medical products, including drugs, devices and biologics that affect American lives on a daily basis. A 2006 report on drug safety by the Institute of Medicine (IOM) made the following observation in a chapter devoted to FDA resources:

> The Food and Drug Administration lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future.... There is little dispute that FDA in general is ... severely underfunded.[1]

Several individuals who previously held high-ranking positions in FDA or the Department of Health and Human Services (HHS) have organized advocacy groups to lobby for increased funding for the entire agency.[2] These groups present data to support their position that FDA has fallen behind in overall funding in the last 25 years. They warn that the agency is at risk of being unable to adequately fulfill the many statutory responsibilities that Congress has assigned it. While the call for more resources has been heard from many quarters, including some in Congress, some agency critics are concerned about inefficiencies within FDA and that it needs to do a better job managing its resources.[3]

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[1] Institute of Medicine (IOM), *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, Alina Baciu, Kathleen Stratton, Sheila P. Burke, Editors, Committee on the Assessment of the US Drug Safety System, Board on Population Health and Public Health Practice (Washington, DC: National Academies Press, 2006), p. 193.

[2] The Coalition for a Stronger FDA, at [http://www.fdacoalition.org], and the FDA Alliance, at [http://www.StrengthenFDA.org]. In December 2007 the boards of these two groups announced their intention to merge; details of the merger have not been finalized. Coalitions Lobbying for More FDA Money Are Merging, *FDA Week*, v. 13, December 14, 2007.

[3] IOM, *The Future of Drug Safety*, 2006, p. 81; and, DeLauro Statement on FDA Science Board Report, December 3, 2007, at [http://www.house.gov/delauro/press/2007/December/Science_Board_12_3_07.html].

In general, former FDA Commissioners and interest groups argue that FDA is underfunded for its mission. Calls for cutting the FDA budget or maintaining it at the current level come from organizations, like CATO and the Hoover Institute, that propose limitations on FDA's authority and, therefore, the need for funding. The main voices in support of FDA budget levels, past and present, have been representatives of the various presidential administrations. Over the last 25 years, incumbent FDA Commissioners, when asked during congressional hearings about the adequacy of the FDA budget, have testified that the budget is sufficient to accomplish the job before the agency. However, in non-congressional venues, those same Commissioners have expressed concerns about the constraints on FDA resources and that the agency's core budget has not increased in concert with its rising responsibilities. They have expressed concern about whether the agency can continue to be considered the world's premier consumer protection agency when it is forced to focus its priorities based on the current level of resources that it receives.[4]

This report examines FDA's appropriations history and traces the evolution of the agency's statutory responsibilities. The information is presented to help inform the ongoing discussion about FDA. *CRS takes no position on whether the agency has in fact the necessary resources to meet all its statutory responsibilities.*

The report first provides an overview of FDA's budget and personnel levels from FY1980 through FY2007.[5] That is followed by a more detailed examination of the budget and personnel level over the same period in each of the agency's major activity areas. For each activity area, the report also summarizes the major pieces of legislation that have been enacted since FY1980. Unless noted otherwise, all budget data have been adjusted for inflation to permit comparison across the 28-year period under investigation. The information presented in this report is intended to facilitate an examination of the impact that congressional decision making has had on the ability of FDA to accomplish its public health mission.

Agency Scope and Congressional Jurisdiction

FDA regulates a wide range of products valued at more than $1 trillion in the U.S. economy. About 25% of American consumer dollars are spent on these FDA-regulated products.[6] As one of the agencies within HHS that comprise the Public Health Service,[7] FDA is responsible for the *safety* of most foods (human and animal)

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[4] Andrew C. Von Eschenbach, State of the FDA, *Food and Drug Law Journal*, v. 62, 2007, p. 423-427; and, Jane E. Henney, Remarks of the Commissioner of Food and Drugs, *Food and Drug Law Journal*, v. 54, 1999.

[5] Congress had not acted on FDA appropriations for FY2008 at the time this report was being prepared. Except for **Figure 4**, the figures in this report do not include FY2008 budget or FTE levels.

[6] Food and Drug Administration (FDA), "Frequently Asked Questions (FAQs)," at [http://www.fda.gov/opacom/faqs/faqs.html].

[7] CRS Report RL34098, *Public Health Service (PHS) Agencies: Background and Funding*, (continued...)

and cosmetics. FDA also regulates both the *safety* and the *effectiveness* of human drugs, biologics (e.g., vaccines), medical devices, and animal drugs.

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, is the principal source of FDA's authority.[8] The agency also derives some of its authority from certain provisions in other laws, most notably the Public Health Service (PHS) Act. Under the PHS Act, FDA licenses biological products[9] and performs other activities, such as setting standards for mammography quality.[10] An extensive list of the public laws that significantly affect FDA activities is in **Table A4** in the **Appendix**.

In addition to statutory responsibilities that directly involve product regulation, the FDA must also comply with statutory requirements affecting all or most federal executive agencies, regarding such matters as information management, strategic planning, performance measurement, financial management, property management, and human resources management.[11] Additional requirements apply only to those agencies, including FDA, that have regulatory responsibilities.[12] FDA's role in implementing provisions of some general federal management laws is substantial. For example, the agency supports more than 50 advisory committees, most of which are mandated in statute and are subject to requirements of the Federal Advisory Committee Act.[13] Also, the agency reports that in FY2006 it processed more than 20,000 information requests pursuant to requirements of the Freedom of Information Act.[14]

The congressional authorizing committees that oversee FDA activities are those with jurisdiction over public health issues: the Senate Committee on Health, Education, Labor, and Pensions, and the House Committee on Energy and Commerce. Because Medicare pays for FDA-regulated products, the agency also falls under the jurisdiction of the Senate Committee on Finance and the House Committee

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[7] (...continued)
by Pamela W. Smith, coordinator; Sarah A. Lister, Donna V. Porter, Bernice Reyes-Akinbileje, Andrew R. Sommers, Ramya Sundararaman, Susan Thaul, and Roger Walke.

[8] P.L. 75-717, 1938, currently 21 U.S.C. § 301 et seq.

[9] PHS Act § 351, 42 U.S.C. § 262.

[10] PHS Act § 354, 42 U.S.C. § 263b.

[11] For a listing of these laws, see CRS Report RL30795, *General Management Laws: A Compendium*, by Clinton T. Brass. Examples of general management laws with which FDA must comply include the Government Performance and Results Act of 1993 and the Data Quality Act.

[12] Examples of regulatory management laws with which FDA must comply include the Administrative Procedure Act and the Regulatory Flexibility Act of 1980.

[13] 5 U.S.C. Appendix. For more information, see "FDA Advisory Committees" at [http://www.fda.gov/oc/advisory/default.htm].

[14] 5 U.S.C. § 552. For more information, see FDA, "Freedom of Information Annual Report — FY2006," at [http://www.fda.gov/foi/foia2.htm].

on Ways and Means. Other committees that exercise oversight roles regarding FDA include the House Committee on Oversight and Government Reform, and the Senate Committees on Aging, Homeland Security and Governmental Affairs, and the Judiciary.

The House and Senate Appropriations Subcommittees on Agriculture have jurisdiction over FDA's appropriations. This arrangement reflects, in part, the agency's origin within the Department of Agriculture as the Bureau of Chemistry in 1862. Since 1940, FDA has administratively been part of federal health agencies, specifically HHS and its predecessors.[15]

Advocates for increasing FDA funding point to this jurisdictional separation of FDA appropriations decisions from the rest of PHS and HHS as a contributing factor to alleged underfunding. In 2002, former Acting FDA Commissioner Michael Friedman recommended moving the FDA budget process from the purview of the agriculture appropriations subcommittees to the Labor, Health and Human Services, Education and Related Agencies subcommittees.[16] Five years later, former FDA Commissioner Frank Young raised the same concern and made the same recommendation in congressional testimony.[17] Former FDA Commissioner Jane Henney made a similar observation in February 2007:

> [T]here are other things Congress can do that directly impact this agency's resources ... if they really wanted to look long and hard, FDA would no longer be under the purview of the Agriculture Appropriations Committees. Those people that serve on those committees do it with honor, but they do it primarily because of their interest in agricultural issues. By the time the allocations come out and the interest of the agriculture areas are satisfied, there are very limited resources that the agency [FDA] can ever hope to receive out of that process. If somebody wanted to do something bold ... it would be looking at appropriations in an area that is more compatible ... with the interests of the members of that committee particularly the ones that oversee health issues.[18]

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[15] For histories of FDA and USDA, see their respective websites, at [http://www.fda.gov/opacom/backgrounders/miles.html] and [http://www.fsis.usda.gov/About_FSIS/Agency_History/index.asp].

[16] Michael A. Friedman, "Strengthening the FDA," *Science*, v. 298, December 20, 2002, p. 2332.

[17] Frank E. Young, statement before the Committee on Oversight and Government Reform, U.S. House of Representatives, May 1, 2007, p. 5, at [http://oversight.house.gov/documents/20070501193917.pdf].

[18] Policy Workshop on Strengthening the FDA, Project on Scientific Knowledge and Public Policy, George Washington University School of Public Health and Health Services, Washington DC, February 21, 2007, transcript at [http://www.kaisernetwork.org/health_cast/uploaded_files/022107_gwu_workshop_transcript2.pdf].

FDA Budget and Personnel

Overall FDA Budget

The primary indicator of FDA resources is its budget. The agency's FY2007 total budget is approximately $2 billion.[19] The total FDA budget, also called the *program level*, consists of (1) direct appropriations and (2) other funds (i.e., funding from other sources that are acknowledged in the appropriations acts). Direct appropriations are the amount of funds that Congress assigns to the agency from the annual total available for appropriations as set by the budget committees. Other funds include reimbursables, cooperative research and development agreement (CRADA) resources, intra- and inter-agency services (such as the Parklawn Computer Center), mammography fees, color certification fees, export certification fees, prescription drug user fees, medical device user fees, and animal drug user fees.

FDA annually prepares budget data for Congress that it presents in the *Justification of Estimates for Appropriations Committees* (*Justification*) documents. FDA transmits its draft through HHS to the White House Office of Management and Budget (OMB). The final *Justification* documents, reflecting any HHS and OMB adjustments, are published with the President's annual budget request to Congress. The final *Justifications* are the major source of FDA budget figures and tables in this report. Like most federal agencies, FDA has, over time, reorganized its structure, activities, and budget accounting, which makes historical budget analysis a difficult endeavor. For further information on the difficulties in compiling a budget history of the agency, and the steps taken to address those problems in this report, see the Methodology section in the **Appendix**.

Until FY1992, direct appropriations formed over 95% of FDA's total program level, with other funds contributing the small remainder. A shift began in FY1992 when Congress authorized: (1) the assessment and collection of user fees from pharmaceutical manufacturers for the review of human drug and biologics applications, and (2) fees for the inspection of mammography facilities. Congress subsequently authorized the collection of user fees for the review of medical device applications in FY2002 and animal drug applications in FY2004. By FY2007, other funds, primarily user fees, accounted for almost a quarter of FDA's total program level budget.

Another indicator of agency resources is personnel, available in the *Justification* documents as the number of full-time equivalent employees (FTEs). This is, however, an imperfect measure of personnel strength because it is not weighted by type of position, pay grade, or responsibility, each of which would provide a different measure of the agency's human resources. FDA has described how adjusting salaries for standard measures of inflation is inadequate because of the unique elements of its staff expenses, such as higher than average employee salaries, cost of health and

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[19] FDA *Operating Plan* for FY2007 (March 2007), reflecting final funding levels under P.L. 110-5, Revised Continuing Appropriations Resolution, 2007.

retirement benefits, and resources required for recruitment and retention.[20] FTE numbers do not include contractors and, therefore, arguably provide only a partial measure of workforce strength. If FDA's use of non-employee workers has changed during the 28-year period covered in this report, the numbers of FTEs may be an inaccurate measure of agency personnel strength if viewed in this light.

Figure 1 shows the total FDA budget (i.e., program level) for FY1980 through FY2007 adjusted to FY2000 dollars.[21] FDA program level is composed of direct congressional appropriations, what FDA calls budget authority, and other funds.[22] Using constant FY2000 dollars allows comparisons of purchasing power over the 28-year period. The stacked bars of the figure show the two broad sources of budget dollars: direct appropriations and other funds (primarily user fees). The figure also provides FTE data over the same fiscal years: FTEs funded by budget authority and total FTEs funded at program level (budget authority plus other funds, primarily user fees).

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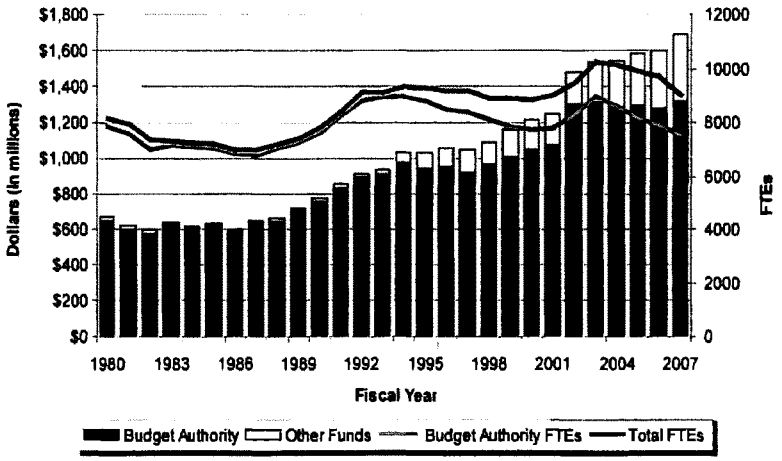
[20] FDA, PDUFA IV proposal, and "PDUFA Fact Sheet," January 11, 2007, at [http://www.fda.gov/oc/pdufa4/factsheet011107.html].

[21] "Total Non-Defense" deflators were used from Table 10.1, Gross Domestic Product and Deflators Used in the Historical Tables: 1940-2012, found in *Historical Tables, Budget of the United States, Fiscal Year 2008*, p. 192-193.

[22] Direct congressional appropriations and funds from user fees (often called offsetting collections) both provide budget authority to FDA. The agency, however, refers to congressional appropriations as budget authority, but not user fee-related sources of funding (which also provide budget authority but are referred to as user fees by FDA).

Figure 1. FDA: Budget and FTEs (Constant FY2000 $)



Source: FDA *Justification of Estimates for Appropriations Committees* documents.

Notes: Total FTEs = Budget Authority FTEs + User Fee FTEs. Program Level $ = Budget Authority $ + User Fees $. FY2007 data is based on a continuing resolution and therefore does not reflect final action by Congress.

As can be seen in **Figure 1**, inflation-adjusted budget authority was relatively flat from FY1980 to FY1988, began to increase from FY1989 until FY1993 when it leveled off, coincident with the introduction of user fees in 1993. **Figure 1** also shows a decline in budget authority FTEs occurred from FY1993 to FY2001, although the total FTEs remained relatively constant due to positions funded by user fees.

Congressional intent in authorizing user fees was that these fees would supplement — rather than replace — resources provided by Congress to FDA. Level funding from Congress — without allowances for inflation, mandatory salary and health insurance increases, as well as other workload-related unfunded mandates — has resulted in declines in FTEs in areas of the agency that do not receive supplemental user fees. A 2002 Government Accountability Office (GAO) report on the impact of user fees resulting from the Prescription Drug User Fee Act (PDUFA) states that:

> According to FDA officials, the agency reduced staffing levels ... to cover the costs of unfunded pay raises. From fiscal years 1994 through 2001, FDA paid about $250 million to cover mandatory federal pay raises for which it did not receive increases in its appropriations. ... [T]his situation reduced the agency's ability to support activities not funded by PDUFA. FDA reduced the staffing levels for non-PDUFA activities each year, leaving the agency fewer resources

> to perform its other responsibilities. For example, in its budget justification for fiscal year 2002, FDA reported that inspection of medical device manufacturers has decreased and the agency does not routinely inspect the manufacturers of lower-risk products. Although FDA staffing in fiscal year 2001 was about the same as in fiscal year 1992, about 1,000 more FTEs were allotted to drug and biologic review activities in fiscal year 2001 and about 1,000 fewer FTEs were allotted to other FDA programs that ensure food safety, approve new medical devices such as heart valves and pacemakers, and monitor devices once on the market.[23]

Figure 1 also shows that budget authority and FTEs increased markedly between FY2001 and FY2002, coincident with increased emergency funding following the domestic terrorist attacks. However, during the FY2002 through FY2007 period, while budget authority remained flat and other funds increased, FTEs once again declined.

In a related matter, the 2002 GAO report expressed concern about attrition among FDA staff which it found to be noticeably greater than in similar disciplines at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).[24] The 2002 GAO report states that:

> [T]he agency continues to experience high turnover for reviewers because of the high demand for regulatory review personnel in the pharmaceutical industry and the higher salaries that experienced FDA reviewers can obtain in the private sector.... FDA officials reported that to retain experienced staff with certain skills, they have increased the pay for approximately 250 [product] reviewers. Specifically, FDA conducted studies of staff turnover and found that toxicologists, pharmacologists, pharmacokinetists, and mathematical statisticians were leaving FDA to work in private industry and academia for higher salaries. Under [federal personnel] regulations, FDA is authorized to pay retention allowance of up to 10 percent of an employee's basic pay to a group or category of employees in such circumstances.[25]

The GAO report also found that "FDA reviewers, particularly those in CBER [Center for Biologics Evaluation and Research], did not participate in training and professional development activities ... to ensure that the agency meets PDUFA goals."[26] The 2006 IOM report commented on the attrition of FDA personnel by stating that "although one explanation for the turnover is that FDA staff leave for promising opportunities in industry ... it is possible that turnover is indicative of a less-than-ideal organizational culture that requires attention."[27]

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[23] U.S. General Accounting Office, *Food and Drug Administration Effect of User Fees on Drug Approval Times, Withdrawals, and Other Agency Activities*, GAO-02-958, September 2002, p. 17-18.

[24] Ibid., p. 21-23.

[25] Ibid., p. 21-22.

[26] Ibid., p. 23.

[27] IOM, *The Future of Drug Safety*, 2006, p. 81.

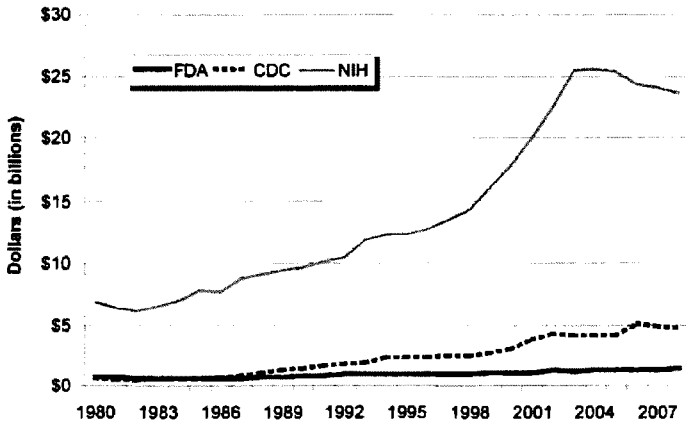
A potential indicator of the difficulty FDA has in keeping experienced staff is the agency's issuance of retention bonuses to some employees. This practice is controversial and is under investigation by the House Committee on Energy and Commerce:

> The payments ... attracted bipartisan criticism from lawmakers ...[who] say that at the FDA, many of the bonuses went to the highest-paid officials rather than the scientists, inspectors and doctors most at risk of jumping to the private sector. To critics, the payments bore little relationship to the agency's performance and reputation or to the likelihood that someone might depart. Agency officials disagree and call the program a success.... In 2002, the FDA lost 12 to 13 percent of its employees, while in 2006, with the bonus program in place, it lost 5 percent.... The bonuses — which are funded in part with fees paid by industry for product reviews — bring no guarantee of retention.[28]

Comparison of FDA Budget with Other Agencies

Figure 2 compares the funding, over time, for FDA, NIH, and CDC, the primary federal agencies with public health duties.

Figure 2. Budget Authority for FDA, CDC, and NIH (Constant FY2000 $)



Source: Office of Management and Budget, Budget Authority file, Public Budget Database, Budget of the United States Government, Fiscal Year 2008. Data available on the OMB website at [http://www.whitehouse.gov/omb/budget/fy2008/db.html]. Does not include FDA offsetting collections (user fees), which have provided an additional 20% to 25% to the FDA budget in recent years.

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[28] John Solomon and Marc Kaufman, "FDA's Retention Bonuses Rise to the Top," *The Washington Post*, August 2, 2007, p. A1.

In FY1980, as shown in **Figure 2**, CDC and FDA had similar funding and NIH funding was sevenfold greater than the other two agencies. Since FY1980, Congress has increased the budget ninefold for CDC, almost fourfold for NIH and about twofold for FDA (in FY2000 adjusted dollars). Other regulatory agencies similar to FDA that are science-based and health-related, such as the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the Consumer Products Safety Commission (CPSC), have received flat or declining budgets (adjusted for inflation) over this same time period.[29]

Concerns raised in the late 1970s about the cumulative effects of federal regulations on business resulted in the substantial changes made by the Reagan Administration in the 1980s in "how federal agencies develop and publish rules, and the degree to which federal regulations were overseen by the Executive Office of the President."[30] The relatively flat funding experienced by FDA and other regulatory agencies may in part be due to the Reagan regulatory reform efforts combined with attempts to control federal spending and shrink the overall size of government.

Former FDA Commissioners, speaking on various public panels, have addressed a perceived need for increasing FDA funding.[31] In prepared testimony for a May 1, 2007 hearing before the House Committee on Oversight and Government Reform, four former FDA Commissioners, Donald Kennedy, Frank Young, David Kessler, and Jane Henney, all agreed that FDA is underfunded. Dr. David Kessler made the following observations on the funding Congress has provided for NIH, CDC and FDA.

> While Congress has attempted to provide resources for burgeoning public health needs on other fronts, support for the FDA has faltered in comparison. In 1986, FDA's budget was comparable to 97% of the budget for CDC and 8% of the NIH's budget. By [2006], it had dropped to 28% of CDC's budget and 5% of NIH's. Significantly, while the NIH's budget to fund the research that leads to discoveries that ultimately fill the FDA's drug pipeline has doubled over the last five years, FDA's budget has not grown.[32]

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[29] For EPA, see Figure 1 in CRS Report RL32856, *Environmental Protection Agency: Appropriation for FY2006*, by Robert Esworthy and David Bearden; for OSHA and CPSC, see budget data available on the OMB website at [http://www.whitehouse.gov/omb/budget/fy2008/db.html].

[30] CRS Report RL32356, *Federal Regulatory Reform: An Overview*, by Curtis Copeland.

[31] Remarks by former FDA Commissioners Jane Henney, Donald Kennedy, and Frank Young at the Policy Workshop on Strengthening the FDA, the SKAPP Project on Scientific Knowledge and Public Policy, George Washington University School of Public Health and Health Services, Washington DC, February 21, 2007, transcript at [http://www.kaisernetwork.org/health_cast/uploaded_files/022107_gwu_workshop_transcript2.pdf]; and Remarks by former FDA Commissioners David Kessler and Mark McClellan at "Public Policy Implications of the Food and Drug Administration Revitalization Act (FDARA)," Center for Congressional and Presidential Studies, American University School of Public Affairs and FORA.tv, Washington DC, September 12, 2007.

[32] David Kessler, "FDA's Critical Mission and Challenges for the Future," testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May

(continued...)

On this same point, former Acting FDA Commissioner Michael Friedman made the following observations:

> It is myopic to fund a minimal FDA when we have doubled the NIH budget roughly every 10 years for the past 40 years ... or when the pharmaceutical industry annually invests more than $30 billion in research and development. Because regulatory review is the final common pathway for all translational medicine, this lack of resources is rate-limiting. I cannot predict everything that our citizens demand from FDA, but I am sure they are not currently getting it. The issue is not what the FDA "needs;" it is rather what the American public deserves.[33]

The 2006 IOM on drug safety report notes that over the years various groups have examined the same questions about the FDA and its budget and have made a variety of proposals and recommendations to improve the agency which have not been fully implemented. The IOM report goes on to state that:

> A primary obstacle ... may be the chronic underfunding of core FDA activities owing to inadequate attention to resource needs by Congress and the Office of Management and Budget.[34]

Some Members of Congress also have expressed concern over the FDA funding level, and have voiced their frustration at the inability to obtain clarification from the agency on the adequacy of the FDA budget. A source of apparent frustration to those Members, including some who serve on the appropriations subcommittees and have indicated their willingness to increase appropriations to the agency, are the FDA officials who, year after year, neither ask for increased funding in their testimony, nor, in response to Members' questions, acknowledge what some observers perceive to be the agency's needs for additional resources. For example, in written testimony regarding the FY2004 proposed budget, FDA Commissioner Mark McClellan stated:

> We believe our budget request will allow FDA to fund ongoing operations at the current level and also support more than 1,000 recently hired investigators and analytical staff to fight counterrorism [sic].... The President's 2004 Budget was developed within a framework that set a proposed total for discretionary spending in 2004, and each agency and program request reflects the Administration's relative priority for that operation, activity or program.[35]

In contrast to the above testimony which occurred when he was Commissioner, *former* FDA Commissioner Mark McClellan made the following statement at a

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[32] (...continued)
1, 2007, p. 2, at [http://oversight.house.gov/documents/20070501193354.pdf].

[33] Friedman, Strengthening the FDA, 2002, p. 2332.

[34] IOM, *The Future of Drug Safety*, p. 18.

[35] Written testimony of Mark McClellan, M.D., Ph.D., Commissioner of the Food and Drug Administration, in U.S. Congress, House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, *FY2004 FDA Budget Request*, hearing, 108th Cong., 1st sess., March 6, 2003, available at [http://www.fda.gov/ola/2003/fy2004budget.html].

March 2007 hearing of the Senate Committee on Health, Education, Labor, and Pensions:

> First, the FDA will need significantly greater appropriations to improve post-market safety. The FDA is over-stretched, and a lack of trained staff and technical capabilities to perform the oversight necessary on thousands of prescription drugs is an even more pressing issue than providing the FDA with new regulatory authorities.[36]

Current FDA Commissioner Dr. Andrew von Eschenbach provided the following statement when commenting on the adequacy of the FY2008 budget at a Senate Appropriations Committee hearing:

> These resources are an essential step in building a 21st century FDA that responds to the new opportunities and new challenges of science and technology. Our budget allows FDA to strengthen the tools we use to ensure the safety of foods, evaluate new products, and better predict — earlier and more accurately — the safety and efficacy of drugs, biologics and medical devices. With these resources, we will work to ensure that Americans enjoy the benefits of personalized medicine, a safe and wholesome food supply, and the promise of a better, healthier future.[37]

The IOM committee that worked on the 2006 drug safety report also was not able to ascertain the agency's funding requirements:

> Convention dictates that federal agencies do not publicly articulate resource needs that differ from those offered in the President's budget, so the [IOM] committee was unable to understand fully what ... FDA leadership estimate[s] is needed to meet current objectives, let alone the expanded responsibilities the committee envisions for the future.[38]

In his May 1, 2007 testimony, former Commissioner Donald Kennedy confirmed this point:

> I hope you and your staff will be diligent about pursuing FDA resource needs. But you may have to rely on grizzled veterans like me, because budget authorities at HHS and OMB specifically prohibit present officials in the agency from speaking out publicly about the need for more funding.... [I]t is important that Americans know, when they hear FDA officials say they are satisfied with their

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[36] Testimony of Mark McClellan, M.D., Ph.D., former FDA Commissioner, in U.S. Congress, Senate Committee on Health, Education, Labor and Pensions, *Prescription Drug Safety and User Fees*, hearing, 110th Cong., 1st sess., March 14, 2007, available at [http://www.cq.com].

[37] Statement of Andrew von Eschenbach, M.D., Commissioner of the Food and Drug Administration, in U.S. Congress, Senate Committee on Appropriations, Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, hearing, 110th Cong., 1st sess., February 27, 2007, available at [http://www.fda.gov/ola/2007/budget0227.html].

[38] Ibid., p. 199.

budget allocations, that they have their fingers crossed underneath the witness table.[39]

Like all federal agencies, FDA's budget history reflects both Administration requests and congressional decisions on appropriations. In general, current and previous Administrations have not argued before Congress for increased FDA funding over the years. In some situations, however, Congress has decided to grant additional funds to agencies above an Administration's request. For example, the relevant House and Senate appropriations bill reports demonstrate that Congress has often chosen to increase NIH funding when the Administration has not requested additional appropriations. Congress is supported and encouraged in its efforts to increase the NIH budget by various health and research advocacy groups which promote their individual causes.

Some agencies are able to bypass budget adjustments made by HHS and OMB via alternative mechanisms. For example, the National Cancer Institute (NCI) at NIH is mandated by the National Cancer Act of 1971 (P.L. 92-218) "to prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Institute's advisory council."[40] The so-called NCI Bypass Budget received by Congress describes the increase required to maintain NCI's present level of operations and the increases required to expand existing initiatives.[41] Similarly, CDC has prepared a "Professional Judgement" budget in response to requests from a congressional appropriations committee.[42]

A regulatory agency, such as the FDA, may be perceived as an impediment to achieving the goals of advocacy groups concerned with the expeditious approval of new drugs or devices for the treatment of specific diseases. However, when a drug or device adverse event occurs, there is heightened concern about FDA's approval process. In general, attention to FDA's state of affairs seems to be dependent on reaction to crisis. The public and Congress tend to focus on the agency when its regulatory processes fail to meet their expectations. This phenomenon is perhaps best exemplified by the thalidomide episode in 1962.[43] However, even significant

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[39] Donald Kennedy, testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May 1, 2007, p. 4, at [http://oversight.house.gov/documents/20070502110032.pdf].

[40] Public Health Service Act, Section 413(b)(9).

[41] U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, *The Nation's Investment in Cancer Research: A Plan and Budget Proposal for Fiscal Year 2008*, October 2006, NIH Publication Number 06-6090, p. 40, at [http://plan.cancer.gov/pdf/nci_2008_plan.pdf].

[42] Centers for Disease Control and Prevention, Professional Judgement for Fiscal Year 2008, April 20, 2007, at [http://www.fundcdc.org/documents/CDCFY2008PJ_000.pdf].

[43] Philip J. Hilts, *Protecting America's Health: the FDA, Business, and One Hundred Years* (continued...)

legislative solutions, such as the Kefauver-Harris Drug Amendments of 1962 (which required demonstration of effectiveness prior to drug approval), were not accompanied by an increase in funding for FDA. In his history of FDA and its regulation of the pharmaceutical industry, Philip J. Hilts, referring to passage of Kefauver-Harris, reported that:

> Unfortunately, when Congress took this step forward, getting serious about science and testing to protect the public, it did what it had often done before: it voted to give the agency new duties and responsibilities while failing to provide the money to allow the agency to carry them out. The error would cause years of dissension and trouble, and would not be remedied for three decades.[44]

Presumably, the remedy Hilts is referring to is PDUFA and the implementation of user fees by FDA in 1993. Some critics argue that user fees have not solved FDA's funding problems and have led to additional complications for the agency.[45] On the other hand, perhaps the way the agency has been managed and the resource structure imposed by statute are contributing to the agency's perceived problems in accomplishing its mission.

FDA Activity-Area Budgets

FDA is organized into six centers, which cover the broad activity areas for which the agency has responsibility, and two offices that perform agency-wide functions.[46] The traditional *activity areas* are somewhat parallel to the current centers. FDA's major activity areas are: Foods; Human Drugs; Biologics; Animal Drugs and Feeds; and, Medical Devices and Radiological Health. This report focuses on the activity areas rather than the centers, to be consistent with the presentation in the historical *Justification* documents. Center names and their activity area responsibilities have changed over time to reflect shifts in agency organization, but the agency's activity areas have stayed fairly constant over the past 25 years.

Although FDA consistently reports its budget recommendations broken out by activity areas, it is not possible, using the publicly available *Justifications*, to determine whether these categories have always included the same activities.

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[43] (...continued)
of Regulation, Alfred A. Knopf, New York, 2003.

[44] Ibid., p. 165.

[45] Frank E. Young, testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May 1, 2007, p. 4, at [http://oversight.house.gov/documents/20070501193917.pdf]; and, Rena Steinzor and Margaret Clune, "The Hidden Lesson of the Vioxx Fiasco: Reviving a Hollow FDA," Center for Progressive Reform, October 2005, at [http://www.progressivereform.org/articles/Vioxx_514.pdf].

[46] The Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), National Center for Toxicological Research (NCTR), Office of the Commissioner (OC) and the Office of Regulatory Affairs (ORA). The organization tables of FDA overall and its components are available at [http://www.fda.gov/opacom/7org.html].

Therefore, as with other federal agencies, it is not always possible to accurately compare categories of budget or staffing over long periods of time. An example of this, as discussed below, is the changing placement of Biologics in the agency's budget. Biologics was encompassed for a time within the Human Drug budget, and FDA's *Justifications* provide no means of separating the two activities. This report contains the most consistent accounting that was possible from the information provided in the FDA *Justifications*.[47] For further information on the difficulties in compiling a budget history of the agency, and the steps taken to address those problems in this report, see the Methodology section in the **Appendix**.

The Office of the Commissioner and the National Center for Toxicological Research do not have direct regulatory responsibilities and, therefore, are only described briefly in this report. Their funding and personnel are included, however, in the FDA totals. The Office of Regulatory Affairs (ORA) conducts FDA's compliance activities, including inspection and enforcement, across all activity areas. The agency's budget justification documents allocate ORA funding to each activity area as "field activities."

Table 1. Summary of Increase in Total Budget and FTEs, FY1980 and FY2006 (Constant FY2000 $)

Activity Area	Measure	FY1980	FY2006	% Increase
Food	Budget	$188,967,000	$376,262,000	99.1%
	FTEs	2,408	2,774	15.2%
Human Drugs	Budget	$143,292,000	$436,454,000	204.6%
	FTEs	2,102	2,947	40.2%
Biologics	Budget	$44,004,000	$169,562,000	285.3%
	FTEs	507	979	93.1%
Animal Drugs & Feeds	Budget	$46,688,000	$83,914,000	79.7%
	FTEs	516	592	14.7%
Devices & Radiological Health	Budget	$97,427,000	$218,732,000	124.5%
	FTEs	1,399	1,498	7.1%
FDA Total[a]	**Budget**	**$675,271,000**	**$1,597,508,000**	**136.6%**
	FTEs	**8,182**	**9,698**	**18.5%**

Source: *FDA Justification of Estimates for Appropriations Committees* documents.

Note: Detailed unadjusted budget amounts and FTE numbers can be found in this report's **Appendix, Table A2,** and **Table A3**.

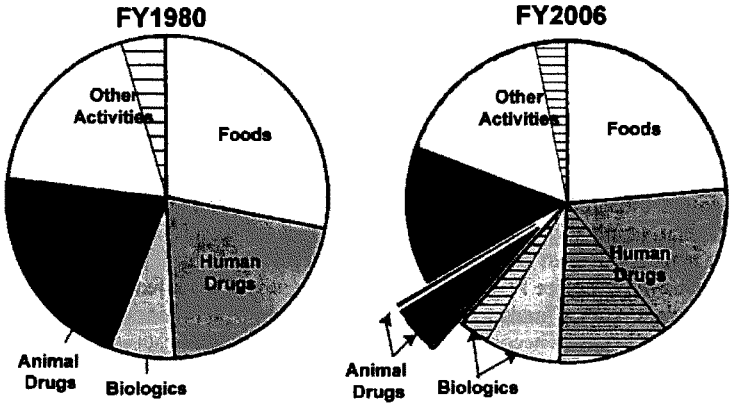
a. Activity area numbers do not add to FDA totals because not all FDA functions are included.

[47] FDA cited constraints on its staff time and indicated that it would only be able to provide data for recent years.

After adjusting for inflation, FDA's total budget increased by 136.6% between FY1980 and FY2006 (see **Table 1**). Over the same period, total FTEs increased by 18.5%. Each activity area within the agency reflects a greater increase in budget than in FTEs during the period. As noted above, tracking FTEs is typically an imperfect measure of changes in an agency's level of effort over time.[48] A variety of factors might account for the differing rates of growth of FDA's budget and staffing. A precise accounting of the possible causes of these differences was not available in FDA budget *Justifications*.[49] Further exploration of the reasons for the differing rates of growth in budget and FTEs is, however, beyond the scope of this report.

Figure 3 compares the FDA budgets for FY1980 and FY2006, displaying the major activity area budgets relative to each other and to the whole agency. The figure also illustrates the relative proportions of the activity-area budgets that user fees finance. In FY2006, user fees comprised 41% of the Human Drugs budget, 30% of Biologics, 8% of Animal Drugs and Feeds, 14% of Devices and Radiological Health, and 0% of Foods. The proportion of the total FDA budget provided in direct appropriations as budget authority was 96% in FY1980 and 80% in FY2006.

Figure 3. FDA Budgets for FY1980 and FY2006, by Major Activity Area and Type of Funding



Source: FDA *Justification of Estimates for Appropriations Committees* documents.

Notes: Total FDA budget without adjustment for inflation was $340 million in FY1980 and $1,863 million in FY2006. "Animal Drugs" is Animal Drugs and Feeds, and "Devices" is Devices and Radiological Health.

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[48] See discussion of FTEs beginning on p. 5.

[49] The authors requested further information from FDA which, as of the date of this report, has not been provided.

Impact of New Statutory Authorities on FDA Budget

New statutory authorities, assigned to specific FDA activity areas, frequently mandate initiatives without resources for implementation. The implementation of major new initiatives requires adequate time and resources to meet congressional intent. Former FDA Commissioner Frank Young indicated that, while he was Commissioner, there were "mandates for 22 new activities without accompanying appropriations," which he categorized as unfunded mandates.[50] He also attested to the difficulty for the agency in the implementation of new statutory language. In the case of implementing the Hatch-Waxman Act for the expeditious evaluation of generic drug products, he stated the following:

> [T]here were major problems in the development of procedures within FDA, inadequate resources available for crafting the regulations, and difficulties in the implementation of the initial ANDA [Abbreviated New Drug Application] processes. Similarly, there were substantial budgetary needs for adequate enforcement of procedures, for approval of products developed by industry during the initial implementation of the act. The agency was in uncharted water.[51]

Likewise, implementation of the FDA Modernization Act of 1997 (FDAMA), required the agency to "develop 42 new regulations, 23 guidances and numerous reports and studies," many within a year.[52] At the time, HHS Secretary Shalala commented on the complications and costs of carrying out the effort, which she estimated to be $50 million.[53]

The $1.58 billion that FDA has collected in prescription drug user fees since FY1993 has helped the agency improve the timeliness of its drug review process. These benefits may mask what some FDA advocates see as PDUFA's distorting effects on within-activity-area budgeting. Congress included in PDUFA an important limitation, often referred to as a trigger, to ensure that the user fees would supplement rather than supplant appropriated funds. To collect and spend the drug user fees, FDA must maintain at least the same level of effort on activities related to human drug review as it had before PDUFA. That limitation would not affect other parts of the FDA budget if other funding were to keep pace with both inflation and the needs of the agency. However, according to FDA documents and the observations of external experts, FDA's financial situation has changed over the 15 years since PDUFA began. FDA has had to use directly appropriated funds to keep the PDUFA-related activities at least constant over time, thereby diverting those funds from other uses.

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[50] Frank E. Young, testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May 1, 2007, p. 6, at [http://oversight.house.gov/documents/20070501193917.pdf].

[51] Ibid.

[52] Jill Wechsler, "The 'R' in CDER and CBER," *Pharmaceutical Technology*, April 1998, p. 14.

[53] Ibid.

FDA financial reports, required under PDUFA, have claimed that this unanticipated PDUFA effect has resulted in "an erosion of core FDA programs."[54]

FDA Regulatory Research

The research program at FDA provides scientific support for regulatory issues addressed by the agency. Research has been a part of the agency almost from the time of its inception in 1906.[55] All five FDA activity areas support research with Foods conducting the largest program, followed by Biologics, Devices and Radiological Health, Animal Drugs and Feeds, and Human Drugs, which has a very small research program. Research performed in the five FDA activity areas comprises about 50% of the FY2006 FDA research budget. Other entities within FDA that perform research are the National Center for Toxicological Research (33%), Office of Orphan Products (11%), Program Management (3%), and Buildings and Facilities (3%).[56] **Figure 4** shows the amount of support for research within the five FDA activity areas from FY1993 through FY2008.

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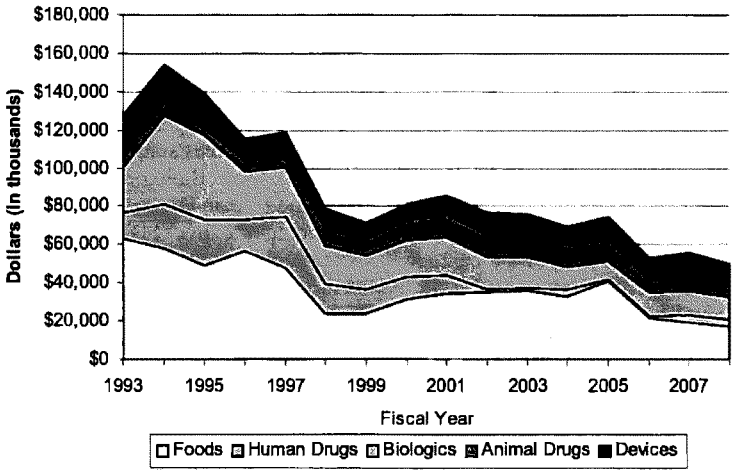
[54] See discussion of "triggers" in Human Drugs section of this report, as well as the FDA *White Paper Prescription Drug User Fee Act (PDUFA): Adding Resources and Improving Performance in FDA Review of New Drug Applications*, at [http://www.fda.gov/oc/pdufa/whitepaper11-10/whitepaper11-10.html], and the *FY2001 PDUFA Financial Report*, at [http://www.fda.gov/oc/pdufa/finreport2001/financial-fy2001.htm], and the *FY2000 PDUFA Financial Report*, at [http://www.fda.gov/cder/pdufa/financial-fy2000.htm], and the *FY1999 PDUFA Financial Report*, at [http://www.fda.gov/oc/oms/ofm/accounting/pdufa/1999Report.htm].

[55] The Bureau of Chemistry established a Food Research Laboratory shortly after it was created in 1906 within the Department of Agriculture. See the Science Board Subcommittee on FDA Research, "Recommendations to the Science Board of the Food and Drug Administration," Final Draft Report, March 13, 1997, Appendix D, "An Abbreviated History of at Least Four Decades of Efforts to Upgrade the Quality of Science in the FDA," at [http://www.cfsan.fda.gov/~frf/sxsbrd.html].

[56] FDA research budget data from RAND Corporation RaDiUS database, November 7, 2007. RaDiUS, which stands for "Research and Development in the United States," tracked all research and development activities and resources of the government from FY1993 through FY2008. Information about the RaDiUS database can be found at [https://radius.rand.org/radius/index.html].

Figure 4. FDA Research in Five Activity Areas (Constant FY2000 $)



Sources: FDA research budget data was provided by Donna Fossum of the RAND Corporation using the RaDiUS database on November 7, 2007. Data collection for RaDiUS began with FY1993. FDA data collected for FY2006 through FY2008 were received by RAND from FDA Office of Budget Formulation and Presentation (OBFP) via Edward King, HHS Office of the Assistant Secretary for Management and Budget, in March 2007. Amounts for Foods for FY2006 through FY2008 were adjusted per personal communication with Robert Miller, FDA-OBFP, on November 19, 2007.

The appropriate role of research in fulfilling FDA's mandate to license and approve safe and effective products has been a contentious issue at least since the early 1970s.[57] At the request of former Deputy Commissioner for Operations Michael Friedman, a review of FDA research was conducted in 1996 by a subcommittee of the FDA Science Board. The Chairman of the subcommittee, Dr. David Korn, stated that "Congress has not been asked to support research explicitly; [research] has always been buried in the agency's budget."[58] Dr. Korn suggested that it would require a major educational effort by industry to convince Congress that research is essential to the function of FDA because "industry is, in a sense, the FDA's customer," and "if the thrust came from industry, it would carry weight with the Congress."[59] The final report of the subcommittee, dated March 1997, stated that:

> The decreasing agency [research] budget is of overarching concern. Although there is general appreciation of the fact that in times of constrained resources the agency must take particular care that its mandated regulatory responsibilities are competently discharged, there is a widely held perception among agency

[57] Charles Marwick, "FDA Funding Problems Imperil Safety of Biological Products in the United States," *Journal of the American Medical Association*, March 25, 1998, p. 899-901.

[58] Ibid., p. 900.

[59] Ibid., p. 901.

> scientists that the research programs do not have strong advocacy at the highest levels of agency leadership and are front-line targets for curtailment or elimination as discretionary resources decline. The subcommittee believes strongly that starving the agency's base of intramural scientific expertise must inevitably compromise the quality of review and regulatory activities.[60]

The role of FDA research and the level of resources required for its support continues to be identified as an issue for the agency. During the May 1, 2007, congressional hearing, the former Commissioners specified the lack of financial support for the research program at FDA as a major concern. Former commissioner Frank Young stated that "research at CBER has been eviscerated through a recent reorganization and is almost non-existent in CDER. To maintain the expertise necessary for expeditious but highly competent decisions on new breakthrough products,... it is essential to have a well trained scientific staff that is given the time to not only maintain scientific expertise but to pursue career development in their chosen field of science."[61] On this same point, former commissioner David Kessler stated that:

> The erosion of funding has struck hard at the Agency's ability to support its proud tradition of groundbreaking research in regulatory science. While in the past, the Agency led the way in developing new scientific paradigms for approving biologics and assessing food contaminants — to the benefit of both industry and consumers — resources for FDA to lend its intellectual firepower to addressing key regulatory questions are increasingly scarce.[62]

FDA Science Board Report

A report that assessed "whether science and technology at the FDA can support current and future regulatory needs" was released in November 2007.[63] The report was requested by FDA Commissioner Andrew von Eschenbach in December 2006 and was prepared by the FDA Science Board, a group of independent advisors. It found that FDA "suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities."[64] The report points at two reasons for the deficiency: the demands on FDA have soared, and resources have not increased in proportion to the demands. It states that "due to constrained resources

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[60] The Science Board Subcommittee on FDA Research, "Recommendations to the Science Board of the Food and Drug Administration," Final Draft Report, March 13, 1997, at [http://www.cfsan.fda.gov/~frf/sxsbr.html].

[61] Frank E. Young, testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May 1, 2007, p. 3, at [http://oversight.house.gov/documents/20070501193917.pdf].

[62] David Kessler, "FDA's Critical Mission and Challenges for the Future," testimony before the U.S. House of Representatives, Committee on Oversight and Government Reform, May 1, 2007, p. 3, at [http://oversight.house.gov/documents/20070501193354.pdf].

[63] FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk*, November 2007, at [http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf].

[64] Ibid., p. 2.

and lack of adequate staff, FDA is engaged in reactive regulatory priority setting or a fire-fighting regulatory posture instead of pursuing a culture of proactive regulatory science."[65]

The FDA Science Board was specifically asked to review the status of science and technology at FDA, and *not* to evaluate the available resources. However, the report states that the status of science and technology was "so intertwined with two decades of inadequate funding that it was impossible to assess technology without also assessing resources."[66] The Science Board also looked at reports on FDA issued by previous review committees, each given a similar charge over the past 50 years. It found that the concerns outlined in past reports were the same as those in the present and that FDA has consistently been unable to implement the needed changes. An advisor to the Science Board, Garret A. FitzGerald, blamed a faction of "congressional majorities and presidential administrations that has serially stripped the agency of assets."[67]

Representative Rosa DeLauro, who in the 110th Congress was appointed chair of the House Appropriations Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, stated that the November 2007 report confirms facts that she believes have been apparent to Congress and FDA for some time. "[S]cience at the FDA is deteriorating and the agency lacks the planning, management structure, and resources to restore their scientific capabilities."[68] She further states that although her subcommittee is working on providing additional funds for the agency, "money alone will not resolve the problems at FDA — these additional funds need to be supported by an adequate management structure and a sound plan on how these funds will be used to ensure that they are not wasted."[69]

The FDA Science Board report concluded that "FDA can no longer fulfill its mission without substantial and sustained additional appropriations," and that the agency is in danger of "losing its remaining dedicated staff" if the "chronic underfunding of the agency" is "not addressed immediately."[70] The report stated that there is "insufficient investment in professional development [for FDA staff], which means that the workforce does not keep up with scientific advances.... Inadequately trained scientists are generally risk-averse, and tend to give no decision, a slow decision or, even worse, the wrong decision on regulatory approval or disapproval."[71] The report also concluded that funding increases recommended by other groups, such

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[65] Ibid., p. 4.

[66] Ibid., p. 6.

[67] Gardiner Harris, "Advisers Say FDA's Flaws Put Lives at Risk," *The New York Times*, December 1, 2007.

[68] DeLauro Statement on FDA Science Board Report, December 3, 2007, at [http://www.house.gov/delauro/press/2007/December/Science_Board_12_3_07.html].

[69] Ibid.

[70] FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk*, p. 7.

[71] Ibid., pp. 4-5.

as IOM and the Coalition for a Stronger FDA, are insufficient to allow all the changes necessary for the agency to fulfill its mission. "Without a substantial increase in resources, the agency is powerless to improve its performance, will fall further behind, and will be unable to meet either the mandates of Congress or the expectations of the American public. This will damage not only the health of the population of the U.S., but also the health of the economy."[72]

Major Activity Areas: Budget and FTEs

The next sections of this report provide, for each FDA major activity area, a brief description of the statutory responsibilities in 1980 and an overview of how the agency's responsibilities have expanded over the years up through 2007. Juxtaposed with the presentation of increasing responsibilities for the activity area is a presentation and analysis of the budget and number of FTEs for the period FY1980 through FY2007.[73] The descriptions of FDA's responsibilities and resources provide a background against which to examine FDA funding needs. Other CRS reports examine the particulars of many FDA activities and their funding.[74]

Foods[75]

FDA is responsible for promoting and protecting the public's health in part by ensuring that the food supply is safe, sanitary, wholesome and accurately labeled. The agency regulates all foods, except for meat and poultry which are regulated by the U.S. Department of Agriculture (USDA).[76] It is also responsible for assuring that cosmetic products are safe and properly labeled. The agency regulated $417 billion worth of domestic food, $49 billion worth of imported food, and $60 billion worth of cosmetics in 2001.[77] These numbers encompass the economic activity of about 50,000 food establishments (manufacturers, processors, and food warehouses) and 3,500 cosmetic firms.[78] Not included in these figures are the roughly 600,000 restaurants and institutional food service establishments and 235,000 supermarkets,

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[72] Ibid., p. 8.

[73] Budget size varies across the activity areas within FDA. The budget range shown in each figure reflects a scale appropriate to allow clear illustrations of the within-activity area budget variation across years.

[74] See a listing of CRS products relating to FDA-regulated foods, human drugs, biologics, devices, animal drugs, and cross-cutting issues at [http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2678] and [http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2621].

[75] This section was prepared by Donna V. Porter, Specialist in Food Safety and Nutrition.

[76] CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker and Donna V. Porter.

[77] FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk*, p. 11.

[78] See [http://www.cfsan.fda.gov.html].

grocery stores, and other food outlets that are regulated by state and local authorities, for which FDA provides guidance, model codes, and other technical assistance.

Although FDA is responsible for ensuring the safety of the food supply, its role is primarily reactive since most foods and their ingredients are not subject to prior approval or even review before they enter interstate commerce. The agency does have responsibility over some product ingredients that require premarket approval, such as food and color additives. FDA also performs postmarket monitoring of food labels and investigates food safety problems that arise. The agency's surveillance program tests food samples to determine if pesticide residues or heavy metals are present in unacceptable amounts. It also sets standards for label information to assist consumers in determining the ingredient and nutrient content of the foods that they are purchasing. The agency's current activities related to foods are primarily conducted by the Center for Food Safety and Applied Nutrition (CFSAN).

The Pure Food and Drug Act of 1906 gave the agency its initial authority to prohibit the interstate commerce of adulterated or misbranded food products, along with the authority to assess criminal penalties for violations and seize offending products. The Federal Food, Drug and Cosmetic Act of 1938 (FFDCA), building on the provisions of the 1906 Act, required the agency to promulgate definitions and standards for foods and informative labeling. It also prohibited false advertising and the addition of substances that would render the food adulterated. Over the years, several amendments to the act added authorities that required FDA to establish (1) tolerances (safe levels) for pesticides on agricultural commodities; (2) premarket approval systems for food and color additives, and packaging substances; (3) rules for labels to facilitate price comparisons; and (4) rules to assure that packages contain the amount of product the label claims.

By FY2007, Congress had added a number of new authorities to those that existed before FY1980 for FDA (see **Table 2**). Under the Infant Formula Act of 1980 (P.L. 96-359) FDA established requirements for the manufacturing, labeling, and nutrient standards for these products. The Nutrition Labeling and Education Act of 1990 (NLEA) (P.L. 101-535) provided authority for (1) mandating nutrition labels on most food products, and (2) following the agency's review, allowing nutrient content and health claims. In addition, NLEA preempted most state and local requirements for labeling, giving FDA responsibility for regulating all aspects of nutrition labeling information. NLEA resulted in the promulgation of a significant number of new regulations and revisions of old rules for consistency with the new authorities. The Dietary Supplement Health and Education Act of 1994 (DSHEA) (P.L. 103-417), provided specific authority for the regulation of supplements and placed the burden of proof on the agency to demonstrate that a supplement already on the market was unsafe and needed to be removed.

The Food Quality Protection Act of 1996 (P.L. 104-170) established a single health-based standard for pesticides in all foods and provided special safety provisions for infants and children. The Food and Drug Administration Modernization Act of 1997 (P.L. 105-115) eliminated premarket approval of food-contact substances (i.e., packaging materials), replacing it with a notification process, along with expanding procedures for FDA authorization of health and nutrient content claims under the NLEA statutory standard.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) required all domestic and foreign facilities that manufacture, process, pack, or hold food for U.S. consumption to register with FDA and maintain records for agency inspection. The act also required prior notice to FDA of products being imported into the United States and provided the agency with administrative detention authority and penalties.

The Food Allergen Labeling and Consumer Protection Act of 2004 (P.L. 108-282) required that a specific statement appear on a food label, when any of the most common allergens are present in a food. In 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (P.L. 109-462) was enacted, which creates a system for reporting to FDA any serious adverse events associated with the use of a dietary supplement, as well as record keeping and inspection authority that may be necessary in cases of a reported adverse event.

Food safety provisions within the Food and Drug Administration Amendment Act of 2007 (P.L. 110-85) required certain processing and ingredient standards as well as the creation of a registry for reportable information on foods with safety problems, allowing for the identification of the supply chain of the questionable food item.

Adjusted for inflation, FDA's foods budget doubled between FY1980 and FY2007; the number of FTEs increased by 15.2% during the same period. Despite substantial increases in statutory authority during the period, FDA's Foods activity did not gain the authority to collect user fees, unlike the other activity areas (discussed below).

Table 2. Foods Statutory Authorities in 1980 and 2007

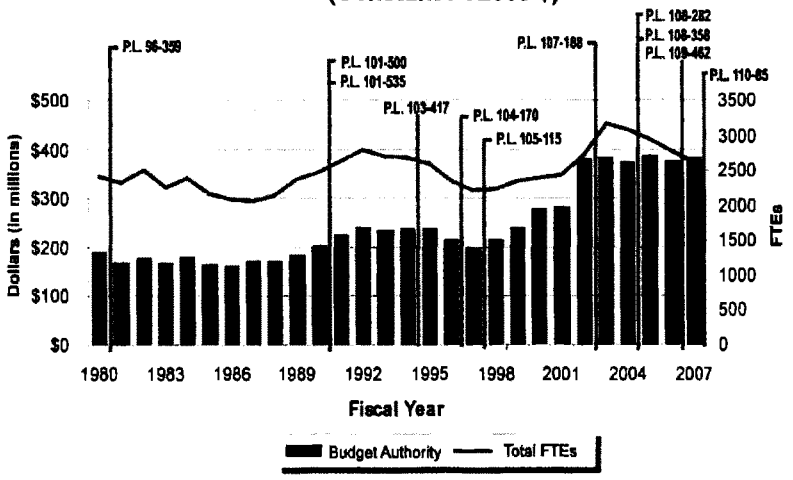
Authorities in 1980
Prohibited interstate commerce in adulterated or misbranded products; provided criminal penalties for violations and authorized seizures of offending products (P.L. 59-384).
Defined filled milk and considered it adulterated, injurious to health and a fraud (P.L. 67-513).
Required the issuing of valid permits for importation of milk and cream (P.L. 67-625).
Required definitions and standards for foods and informative labeling; prohibited false advertising and the addition of substances that rendered the food adulterated (P.L. 75-717).
Provided authority to establish tolerances (safe levels) for pesticides on agricultural commodities (P.L.83-518).
Established premarket approval system for new food additive and packaging substances (P.L. 85-929).
Established premarket approval system for colors used in food, drugs, and cosmetics (P.L. 86-618).
Required rules to prevent non-functional fill of packages and to require legible, prominent label statements for net quantity of contents (P.L. 89-755).

Required inspection of egg products and established uniform standards for grading eggs (P.L.91-597).
Limited authority to regulate the composition and promotion of dietary supplements (P.L. 94-278).
Authorities Added Between 1980 and 2007
Required rules for reporting, quality control, recall, exemption labeling and nutrient content for infant formulas; amended for additional recall, microbiological testing and record retention requirements (P.L. 96-359).
Required assistance with food transportation inspections (P.L. 101-500).
Mandated nutrition labeling and review of nutrient content and health claims; preempted state and local requirements, transferring to FDA the regulation of all aspects of nutrition labeling information (P.L. 101-535).
Provided specific authority to regulate dietary supplements and placed the burden of proof for safety on FDA for products already on the market; required rules for notification for statements of nutritional support, ingredient and nutrition information, petition process and review of new dietary ingredients, and good manufacturing practices (P.L. 103-417).
Required a single health-based standard for all pesticides in raw and processed foods; provided special pesticide safety standards for infants and children; limited consideration of benefits and allowed civil penalties for tolerance violations; required tolerance levels reevaluation in a decade; required endocrine testing, the right to know, and national uniformity of tolerances (P.L. 104-170).
Eliminated premarket approval of food contact substances and substituted a notification process contingent on funding to cover FDA's cost; expanded procedures for authorizing health and nutrient content claims without reducing the statutory standards (P.L. 105-115).
Required all domestic and foreign facilities that manufacture, process, pack or hold food for U.S. consumption to register and maintain records for inspection for any product believed to be adulterated; required prior notice of products being imported into the United States; provided administrative detention authority and penalties for credible evidence that a product presents a threat of serious adverse health consequences or death to humans or animals (P.L. 107-188).
Required a specific statement about most frequent allergens to appear on the label when any of those allergens are present in a food (P.L. 108-282).
Reclassified as controlled substances any product containing an anabolic steroid or a precursor that would be converted to a steroid in the body (P.L. 108-358).
Required the reporting to FDA of any serious adverse events that result from the use of a dietary supplement or nonprescription drug; provided record keeping requirements and inspection authority needed for an investigation (P.L. 109-462).
Required the creation of a registry for reportable information on foods with safety problems that allows for identification of the supply chain of the reportable food (P.L. 110-85).

In **Figure 5**, changes in the foods budget and FTEs reflect certain events and policy initiatives during the 27-year period. The budget was relatively flat through the 1980s with requests primarily for mandatory costs and no program increases. The increase in budget and FTEs in the early 1990s reflect the considerable amount of

work required to implement NLEA and the simultaneous CFSAN reorganization. Food safety activities also contributed to the modest increase in FTEs and funding. The subsequent drop off of FTEs from FY1992 to FY1997 represents both deficit reduction efforts and a shift in FTEs to elsewhere in the agency as noted in the 2002 GAO report. The new CFSAN building opened in College Park, MD, in 2001; construction costs were part of the budget increases from 1997 until 2001. Increases in both funding and FTEs in the late 1990s also signaled President Clinton's food safety initiative. Increases in the FY2002 budget and FY2003 FTEs represent increased agency attention to the food supply following the domestic terrorist attacks and subsequent passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. However, the increases did not continue. The foods budget has remained flat, while the number of FTEs has decreased since FY2002. Another reorganization of the foods portion of the agency occurred after 9/11 as a result of a reordering of the Center's work and priorities. Recent concerns about food safety problems have drawn attention to both the foods budget and FTEs.[79]

Figure 5. Foods: Budget and FTEs (Constant FY2000 $)



Source: FDA *Justification of Estimates for Appropriations Committees* documents.
Notes: Total FTEs = Budget Authority FTEs. Program Level $ = Budget Authority $.

Human Drugs[80]

No manufacturer may offer a prescription or over-the-counter drug for sale in the United States without first obtaining FDA's approval. The agency's Center for Drug Evaluation and Research (CDER) works with a manufacturer throughout the

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[79] For more information, CRS Report RS22779, *Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007*, by Donna V. Porter.

[80] This section was prepared by Susan Thaul, Specialist in Drug Safety and Effectiveness.

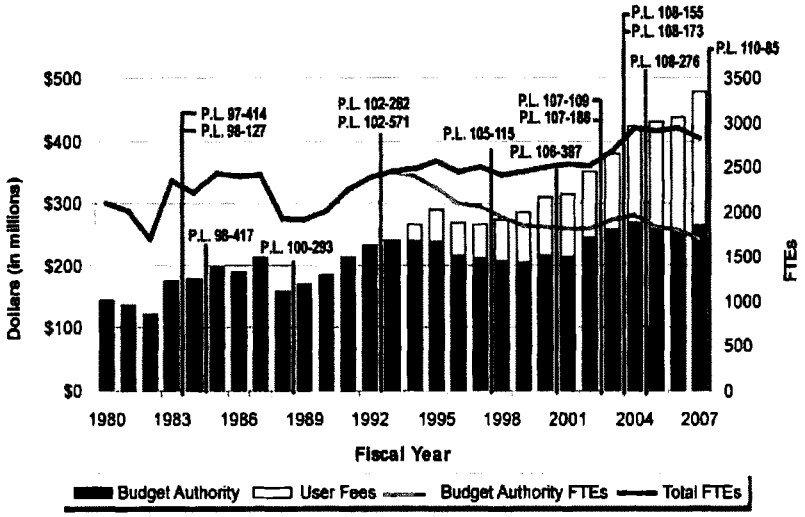
application process, from permitting human clinical trials of an Investigational New Drug (IND), to evaluating for evidence of safety and effectiveness the data from those trials that are part of a New Drug Application (NDA). Up to a drug's approval, CDER wields tremendous influence, as the law authorizes, on required studies for the decision to grant marketing approval (hence, known as "premarket approval" or "premarket review"), wording and layout of materials for the prescribing clinician and the patient, and other aspects of the drug's labeling.

Once a drug is on the market — a period known as both "postmarket" and "postapproval" — FDA continues its activities to ensure the product's safety and effectiveness, although the law does not provide the agency with postapproval authority equivalent to its preapproval function. FDA staff examine the results of studies conducted and submitted by manufacturers; review adverse event reports from manufacturers, clinicians, and consumers; follow the scientific literature regarding other drugs with similar mechanisms of action; and review labeling, packaging, and promotional items to both consumers and clinicians. CDER staff also analyze data that the manufacturer submits and look for trends in large databases of pharmaceutical use.

Figure 6 illustrates the resource history of the FDA Human Drugs program from FY1980 through FY2007. Between FY1980 and FY2007, the total inflation-adjusted funding available for FDA human drug activities increased 234% (that is, it more than tripled) and the number of FTEs increased 34%.[81]

[81] **Table A2** in the **Appendix** displays the actual numbers (not adjusted for inflation). Using the unadjusted numbers, FDA's budget increased almost eightfold (690%) between FY1980 and FY2007. When the dollar figures are adjusted to indicate comparable purchasing value, the increase diminishes to more than threefold (234%).

Figure 6. Human Drugs: Budget and FTEs (Constant FY2000 $)



Source: FDA *Justification of Estimates for Appropriations Committees* documents.

Notes: From FY1983 through FY1987, the appropriations acts and the FDA-produced budget justifications included funding for biologics activities in the human drug activities totals. Therefore, **Figure 6** shows a peak in those years and **Figure 7** shows a concomitant trough for biologics. Total FTEs = Budget Authority FTEs + User Fee FTEs. Program Level $ = Budget Authority $ + User Fees $.

Beginning in FY1994, user fees have made up an increasing proportion of FDA's budget for human drug activities. While total funding has increased over the period, this has been entirely due to the increase in user fees. Congressional appropriations have remained essentially flat.

Separating FTEs by funding source shows that the overall increase in personnel comes solely from the user fees first collected in FY1993 and that the overall increase in FTEs obscures a 19% *decrease* in congressionally funded (budget authority) personnel from FY1992 to FY2007.

The 1992 Prescription Drug User Fee Act, in providing FDA with an additional source of funding, explicitly stated that the funds were to supplement, not supplant congressional appropriations. The law included complex formulas, known as "triggers," to enforce that goal. FDA may collect and use fees only if the direct appropriations for the activities involved in the review of human drug applications and for FDA activities overall remain funded at a level at least equal to the pre-PDUFA budget, adjusted for inflation as specified in the statute.

These triggers, in particular, and the relative contributions of appropriations and user fees to FDA's budget for human drugs have implications for budget planning

both within the human drugs activity area and in agency-level decisions across all activities.

The drug-related tasks for which FDA is responsible have evolved along with the social, economic, scientific, and technologic developments in the United States. Even before there was a Bureau of Chemistry in the Department of Agriculture (established in 1862, the ancestral origin of the current FDA), Congress passed legislation to "prevent the importation of adulterated and spurious drugs and medicines." The 1906 Food and Drugs Act heralded the future influence of the federal government on drug (and food) regulation to protect the public's health. Many laws followed (see brief descriptions in the **Appendix, Table A4**). Among the most significant are: the 1938 FFDCA, which required that drugs be safe; and the 1962 Kefauver-Harris Amendments to the FFDCA, which required that drugs also be effective.

Subsequent laws aimed to boost pharmaceutical research and development; to speed the approval of new medicines, including by supplementing FDA resources with user fee revenue; and to encourage research in pediatric drugs; among many other things. Between FY1980 and FY2007, Congress added to FDA's responsibilities new areas (or expanded existing ones) that involved scientific, legal, and enforcement expertise (see **Table 3**). Most recently, the FDA Amendments Act of 2007 (P.L. 110-85) amended dozens of FFDCA sections. These included human drugs provisions to reauthorize certain programs (such as the assessment, collection, and use of prescription drug user fees); to enhance FDA's authority in ensuring safety and effectiveness over a product's life (both pre- and postapproval). It required the Secretary to maintain an Internet website with extensive drug safety information. New authorities include civil monetary penalties for failure to comply with certain postmarket study, labeling, and television advertisement requirements; mandates and incentives for pediatric drug research and labeling; and requirements for making available to the public material such as minutes of agency-industry performance goal negotiations, pediatric assessment findings and reviews, reviews of adverse event reports and advisory committee recommendations on action.

Table 3. Human Drugs Statutory Authorities in 1980 and 2007

Authorities in 1980
Inspect drugs from abroad for quality, purity, and fitness for medical purposes (30th Congress; predates use of the current public law numbering format).
Regulate interstate commerce in food, drink, and drug products; prohibit adulteration and misbranding (P.L. 59-384), including false statements of curative or therapeutic effect (P.L. 62-301).
Review evidence of safety (P.L. 75-717) and effectiveness (P.L. 87-781) before approving a drug for interstate commerce.
Require records of shipments; inspect manufacturing, processing, packing, or holding facilities, including equipment, materials, containers, and labeling (P.L. 75-717, expanded by P.L. 83-217).
Certify batches of color additives (P.L. 75-717); promulgate regulations for the listing of color additives in or on drugs (or other FDA-regulated products) based on conditions, uses, and labeling to assure safe use (P.L. 86-618).
Enforce enhanced labeling and packaging requirements (P.L. 75-717).
Test and certify each batch of insulin (P.L. 77-366) and penicillin (P.L. 79-139) for strength, quality, and purity; promulgate regulations covering, among other things, standards and tests.
Regulate certain drugs as prescription-only (P.L. 82-215).
Regulate prescription drug advertising (P.L. 87-781).
Regulate all antibiotics (P.L. 87-781).
Enforce enhanced regulations covering manufacture, recordkeeping, inspections, prescription refills, of depressant and stimulant drugs; authorized to appoint expert advisory committees (P.L. 89-74).
Enforce enhanced labeling requirements (P.L. 89-755).
Notify Attorney General when a submitted new drug application involves a drug with an abuse potential (P.L. 91-513).
Authorities Added Between 1980 and 2007
Provide incentives for pharmaceutical manufacturers to develop drugs, biotechnology products, and medical devices for the treatment of rare diseases and conditions (P.L. 97-414).
Investigate tampering with packaged consumer products (P.L. 98-127).
Review generic drug applications (P.L. 98-417).
Promulgate and enforce enhanced regulations on the distribution of drug samples (P.L. 100-293, expanded by P.L. 102-282).
Assess and collect fees from the pharmaceutical manufacturers and use the resulting revenue to support its review of new drug applications (P.L. 102-571, P.L. 105-115, P.L. 107-188, P.L. 110-85).
Establish fast track approval process for drugs that would treat life-threatening conditions (P.L. 105-115).
Streamline the drug review process and provide a means for resolving controversial

Authorities Added Between 1980 and 2007
scientific issues (P.L. 105-115).
Enforce refined requirements regarding the dissemination of information about "off-label" uses of drugs or devices not yet approved by the FDA, patient access to investigational therapies, international harmonization and national uniformity in the regulation of nonprescription drugs and cosmetics (P.L. 105-115).
Conduct regulatory functions under a mission statement that will obligate it to maintain a public health protection role while seeking to expedite the marketing of regulated products (P.L. 105-115).
Grant a manufacturer an additional six months of marketing exclusivity in exchange for completing FDA-requested studies of use in children (P.L. 105-115; expanded by P.L. 107-109, P.L. 110-85).
Establish program allowing pharmacists and drug wholesalers to import lower-priced prescription drugs from specific countries. [Not implemented due to trigger requirement.] (P.L. 106-387, P.L. 108-173).
Require a pediatric assessment of safety and effectiveness as part of an application to market a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration for a drug or biologic, or, if the Secretary considers it necessary, for an approved drug or licensed biologic (P.L. 108-155, expanded by P.L. 110-85).
Study the use of technologies to provide prescription drug information to the blind and visually impaired (P.L. 108-173).
Expedite review of countermeasures to chemical, biological, and nuclear agents that may be used in a terrorist attack (P.L. 108-276).

Biologics[82]

Biologics are medical preparations made from living organisms. Examples of such products include traditional biologics (such as vaccines, blood, blood products, antitoxins, and allergenics[83]) and human therapeutic agents produced by the biotechnology industry (such as insulin, interferon, growth hormone, and epoetin). FDA ensures the purity and effectiveness of biologics by (1) issuing a license for each new product that is shown to be safe, pure, and potent and (2) inspecting manufacturing facilities to assure the product continues to be safe, pure and potent. Unlike most chemically synthesized drugs (e.g., aspirin) with a known structure, biologics are often complex mixtures that are not easily identified or characterized. Biologics might also be living entities, such as cells and tissues. Biologics may be isolated from a variety of natural sources (human, animal, or microorganism) or may be produced by biotechnology methods and other cutting-edge technologies. FDA is also responsible for the safety of the nation's blood supply and routinely examines blood bank operations for record keeping and testing of donations for contaminants.

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[82] This section was prepared by Judith A. Johnson, Specialist in Biomedical Policy.

[83] Allergenics are extracts used to diagnose and treat allergic reactions such as hay fever.

Regulatory responsibility for biologics was first delegated in the early 1900s to the Hygienic Laboratory, a precursor of the National Institutes of Health (NIH).[84] In 1972, regulatory authority for biologics was transferred from the NIH Division of Biological Standards to the FDA Bureau of Biologics.[85] During the early 1980s, the FDA merged the Bureau of Drugs and the Bureau of Biologics to form the National Center for Drugs and Biologics. In 1984, all of the "National Centers" within FDA were redesignated simply as "Centers." In 1987, the FDA's Center for Drugs and Biologics was split into the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). CBER continues to use NIH facilities and buildings until the expected move in 2012 to the new FDA headquarters in White Oak, MD.

Because biotechnology products frequently cross the conventional boundaries between biologics, drugs, and devices, determining the jurisdictional status of these new products has been difficult for both the FDA and industry. Some products have had characteristics that met multiple statutory and scientific definitions. In 1991, the FDA published an Intercenter Agreement between CBER and CDER. In general, the agreement stated that traditional biologics as well as most biotechnology products, would be regulated by CBER.[86] In 2002, however, the FDA announced its intention to reorganize review responsibilities, consolidating review of new pharmaceutical products under CDER; CBER retains review responsibility for vaccines, blood safety, gene therapy, and tissue transplantation.[87] On June 30, 2003, responsibility for most therapeutic biologics was transferred from CBER to CDER.[88] Remaining at CBER are traditional biologics such as vaccines, allergenic products, antitoxins, antivenins, venoms, and blood and blood products, including recombinant versions of plasma derivatives (clotting factors produced via biotechnology).

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[84] The NIH Almanac — Historical Data: Chronology of Events, at [http://www.nih.gov/about/almanac/historical/chronology_of_events.htm].

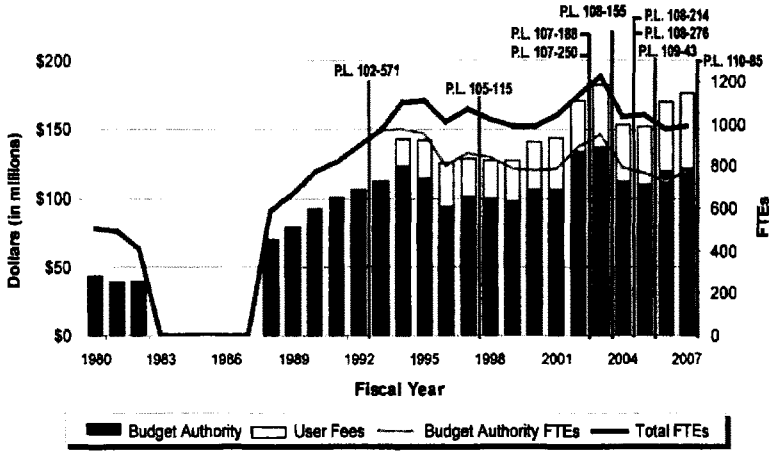
[85] Donna Hamilton, "A Brief History of the Center for Drug Evaluation and Research," FDA History Office, November 1997, at [http://www.fda.gov/cder/about/history/Histext.htm].

[86] Except for a small set of biologics (hormones, such as insulin, human growth hormone, and a few medical enzymes) that would continue to be regulated by CDER. These biologics have historically been regulated as drugs under the Federal Food, Drug and Cosmetic Act rather than licensed under the Public Health Service Act.

[87] FDA Press Release, "FDA to Consolidate Review Responsibilities for New Pharmaceutical Products," September 6, 2002, at [http://www.fda.gov/bbs/topics/NEWS/2002/NEW00834.html].

[88] *Federal Register*, v. 68, no. 123, June 26, 2003, pp. 38067-38068. Examples of products transferred to CDER include monoclonal antibodies; proteins intended for therapeutic use (interferons, thrombolytic enzymes); immunomodulators (other than vaccines and allergenic products); and growth factors, cytokines, and monoclonal antibodies intended to alter production of blood cells. See Transfer of Therapeutic Products to the Center for Drug Evaluation and Research [http://www.fda.gov/cber/transfer/transfer.htm]; Approved Products Transferring to CDER [http://www.fda.gov/cber/transfer/transfprods.htm]; and, Therapeutic Biological Products [http://www.fda.gov/cder/biologics/default.htm].

Figure 7. Biologics: Budget and FTEs (Constant FY2000 $)



Source: FDA *Justification of Estimates for Appropriations Committees* documents.

Notes: For FY1983 through FY1987, FDA managed Biologics activities and Human Drugs activities in one Center. The *Justifications* for those years provide only combined dollar and FTE numbers, which are included in **Figure 6** (Human Drugs) and not in **Figure 7** (Biologics). Total FTEs = Budget Authority FTEs + User Fee FTEs. Program Level $ = Budget Authority $ + User Fees $.

Figure 7 shows the total FDA budget for Biologics, composed of budget authority and user fees, for FY1980 through FY2007, adjusted to FY2000 dollars. It also provides FTE data over the same years: FTEs funded by budget authority; and total FTEs funded at program level (budget authority plus user fees). The impact on funding and FTEs of the FDA reorganization in the 1980s can be clearly seen in **Figure 7**. Although budget authority and FTEs for biologics were rising in the late 1980s and early 1990s, the graph shows that both decline and then remain flat coincident with the introduction of user fees in 1993. Budget authority and FTEs increased between FY2001 and FY2003, coincident with increased emergency funding following the domestic terrorist attacks. The drop in biologics funding and FTEs from FY2003 to FY2004 is due to the reorganization of review responsibilities for therapeutic biologics. Following the reorganization, budget authority and FTEs for biologics have remained relatively flat.

FDA's responsibilities related to the approval and regulation of biological products have changed somewhat between 1980 and 2007 (see **Table 4**). In 1980, FDA's authority with respect to the approval of biological products was governed primarily by Section 351 of the Public Health Service Act (P.L. 78-410). In addition, because most biological products also meet the definition of "drugs," they are subject to regulation under the FFDCA (P.L. 59-384). FDA also regulates medical devices involving biologics under various medical device laws. Examples include devices

used in blood banks to produce various blood products, such as automated cell separators, empty plastic containers and transfer sets, and blood storage refrigerators and freezers.

By 2007, the passage of additional laws had created more responsibilities and authorities for FDA in the area of biologics. The Pediatric Research Equity Act of 2003 (P.L. 108-155) requires a pediatric assessment of safety and effectiveness as part of an application to license a new biologic, or, if the Secretary considers it necessary, for an already licensed biologic. The Project Bioshield Act of 2004 (P.L. 108-276) requires FDA to provide an expedited review of vaccines and other countermeasures to bioterrorism agents.

Congress is also currently considering proposed legislation that would expand the agency's regulatory activities by opening a pathway for the approval of so-called follow-on biologics, which are similar, but not identical to the brand-name products made by the pharmaceutical or biotechnology industry.[89] The new regulatory pathway would be analogous to the FDA's authority for approving generic chemical drugs under the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 84-417), often referred to as the Hatch-Waxman Act. FDA personnel have been actively involved for some time in working with Congress on this potential new responsibility.

Table 4. Biologics Statutory Authorities in 1980 and 2007

Authorities in 1980
Licenses new biological products that are shown to be safe, pure, and potent and inspects manufacturing facilities to assure the product continues to be safe, pure, and potent (P.L. 78-410).
Regulates medical devices involving blood products or other biologics (P.L. 75-717).
Regulates biological products (P.L. 87-781).
Regulates advertising of biological products (P.L. 87-781).
Authorities Added Between 1980 and 2007
Assesses and collects fees from biologics manufacturers and uses the resulting revenue to support the review of new biologic products (P.L. 102-571, P.L. 105-115, P.L. 107-188).
Collect user fees for premarket device review (P.L. 107-250, P.L. 108-214, P.L. 109-43).
Requires a pediatric assessment of safety and effectiveness as part of an application to license a new biologic, or, if the Secretary considers it necessary, for a licensed biologic (P.L. 108-155).
Expedites review of countermeasures to agents that may be used in a terrorist attack (P.L. 108-276).

[89] For further information, see CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by Judith A. Johnson.

Animal Drugs and Feeds[90]

The FDA Center for Veterinary Medicine (CVM) regulates animal feeds (such as livestock feeds and pet foods), and veterinary drugs and devices.[91] CVM is responsible for premarket approval of veterinary drugs, based on a sponsor's demonstration of safety and effectiveness. CVM regulates veterinary devices, but does not require their premarket approval.[92] Veterinary biologics are regulated by the USDA.[93] Much of CVM's authority is based in FDA's general authorities in the FFDCA, such as the authority to take enforcement actions if a regulated product is adulterated, to require facility registration, and to conduct inspections. For example, animal feed is included in the definition of "food" in Section 201 of the FFDCA, and must meet the same general standards of safety as human food, pursuant to Sections 401 et seq. of the act. Additional specific requirements may also be applied to CVM-regulated products.

Though USDA and FDA-CFSAN have primary responsibility for the safety of products intended for human food,[94] CVM is responsible for some specific aspects of the safety of human foods derived from animals, such as determining tolerances (safe levels) of certain chemicals in meat and poultry, and evaluating the food safety aspects of animal clones and their offspring. Also, before CVM approves an animal drug, its use in animals must be shown to be safe for humans as well. Drug sponsors must demonstrate that a method is available to detect and measure any drug residues left in edible tissues of food-producing animals. Farmers and veterinarians who use drugs on food-producing animals must adhere to guidelines about how much time must elapse before a treated animal can be slaughtered, or before its milk can be marketed, and any other constraints or warnings that are stated on the drug label.

Figure 8 shows the total FDA budget for animal drugs and feeds, composed of budget authority and user fees, for FY1980 through FY2007, adjusted to FY2000 dollars.[95] **Figure 8** also provides FTE data over the same period: FTEs funded by

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[90] This section was prepared by Sarah A. Lister, Specialist in Public Health and Epidemiology.

[91] See [http://www.fda.gov/cvm/].

[92] FDA can take appropriate regulatory action if a veterinary device is misbranded, mislabeled or adulterated. Also, firms that manufacture radiation-emitting veterinary devices must register their products under the radiological health regulations, administered by the FDA Center for Devices and Radiological Health (CDRH). See FDA CVM, "How FDA Regulates Veterinary Devices," May 2003, at [http://www.fda.gov/cvm/regofdevices.htm].

[93] Veterinary biologics, such as vaccines and clinical laboratory tests, are regulated by the USDA, Animal and Plant Health Inspection Service, Center for Veterinary Biologics. See [http://www.aphis.usda.gov/animal_health/vet_biologics/].

[94] See CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker and Donna V. Porter.

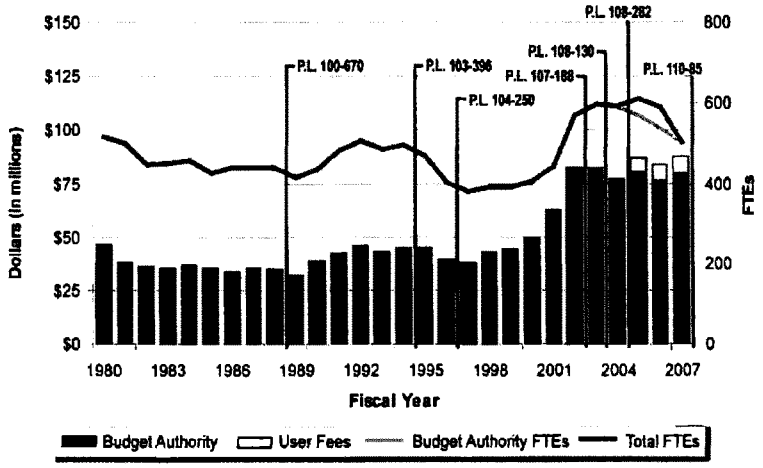
[95] Though CVM was called the Bureau of Veterinary Medicine prior to 1984, the Center and the Animal Drugs and Feeds budget line have, for practical purposes, encompassed the same

(continued...)

budget authority; and total FTEs funded at program level (budget authority plus user fees). During that time, the budget in adjusted dollars increased from $46.7 million in FY1980 to $87.6 million in FY2007. FTEs totaled 516 in FY1980, and 619 in FY2007, though there were fewer than 500 FTEs for most of the intervening years. Drug user fees provided a small portion of CVM's overall budget between FY2004 and FY2007, and made up about 11% of the FY2007 total. (FDA did not have authority to collect user fees for new animal drug reviews until FY2004.)

The budget for animal drugs and feeds, in adjusted dollars, almost doubled in the three-year period from FY1999 to FY2002, from $44.3 million to $82.4 million. FTEs increased from 393 to 570 in the same period. (The budget was relatively stable in the years before and after this period of growth, when adjusted for inflation.) The funding increases largely paralleled increasing budget requests for those years. Increases were requested to support new statutory requirements as well as several initiatives, some of which were agency-wide. These initiatives included activities in food safety, antimicrobial resistance, and postmarket surveillance of drug safety, as well as efforts to reduce drug review times. They also included a bioterrorism preparedness initiative, and the expansion of feed safety programs to protect against Bovine Spongiform Encephalopathy (BSE, or "Mad Cow disease"). In each case, funding was expanded *prior to* a related high-profile incident, namely the 2001 anthrax attacks, and the 2003 emergence of BSE in North America.

Figure 8. Animal Drugs and Feeds: Budget and FTEs (Constant FY2000 $)



Source: FDA *Justification of Estimates for Appropriations Committees* documents.

Notes: Total FTEs = Budget Authority FTEs + User Fee FTEs. Program Level $ = Budget Authority $ + User Fees $.

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[95] (...continued)
activities for several decades, and references to each are used interchangeably.

Prior to 1980, CVM was responsible for evaluating veterinary drugs for approval based on demonstrations of safety and efficacy, and for assuring the safety of animal feeds and feed additives. Several laws enacted since 1980 were aimed at improving the availability of veterinary drugs (which are typically not as lucrative for sponsors as are human drugs), clarifying the use of human drugs in animals, or streamlining the drug approval process. FDA's authority for animal products generally begins with the same statutes as those that regulate human drugs and foods (see **Table 2** and **Table 3**), with additional specific requirements applied in some cases.[96] This is consistent with FDA's long-standing obligation to assure that veterinary drugs and animal feeds are manufactured and used in ways that are safe for *both* animals and humans.

Major laws affecting CVM's regulation of animal drugs and feeds are summarized in **Table 5**.[97] In 1988, the Generic Animal Drug and Patent Term Restoration Act (P.L. 100-670) authorized abbreviated applications for generic new animal drugs. In 1994, the Animal Medicinal Drug Use Clarification Act (P.L. 103-396) permitted veterinarians to prescribe, for animals, extra-label uses of certain approved animal and human drugs, under certain conditions. In 1996, the Animal Drug Availability Act (P.L. 104-250) granted FDA more flexibility in evaluating and approving new animal drugs by amending the definition of substantial evidence of effectiveness. Among other provisions, the law also permitted the use of veterinary drugs in animal feeds, with veterinary prescription.

In 2002, the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188) required the registration of all domestic and foreign facilities that manufactured, processed, packed or held animal feeds.[98] In 2003, the Animal Drug User Fee Act (P.L. 108-130) authorized FDA to collect fees for the review of certain animal drug applications.[99] In 2004, the Minor Use and Minor Species Animal Health Act (P.L. 108-282) authorized, along with other approaches and incentives for limited-market drugs, the conditional approval for drugs to treat minor animal species and uncommon diseases in major animal species,[100] which allows the sponsor to make a drug available before collecting all necessary

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[96] An exception to this general rule is the Dietary Supplement and Health Education Act (DSHEA) of 1994, which requires that FDA not designate substances added to "food for humans" as food additives or drugs if the product meets the definition of a dietary supplement. FDA has interpreted that DSHEA does not apply to products added to animal feeds. Consequently, CVM regulates any animal feed supplement as either a food, food additive, or animal drug, depending on the intended use, and does not apply the additional dietary supplement category.

[97] The Center's statutory authorities are discussed in greater detail on a public website, "Chronological History of CVM," at [http://www.fda.gov/cvm/chronological.htm].

[98] The law applied similarly to human food facilities.

[99] The law is similar to the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA) for human products, and sunsets after October 1, 2008.

[100] For more information on minor uses and minor species, see [http://www.fda.gov/cvm/minortoc.htm].

effectiveness data, but after proving that the drug is safe. In 2007, the FDAAA (P.L. 110-85) required, for pet foods, the development of ingredient, processing and labeling standards, and a surveillance system to detect disease outbreaks. Additional provisions that apply to both human foods and animal feeds require, among other things, that FDA establish a reportable food registry, and that persons in charge of FDA-registered food facilities report any instances of tainted foods that may harm humans or animals.

Table 5. Animal Drugs and Feeds Statutory Authorities in 1980 and 2007

Authorities in 1980
Prohibits interstate commerce in adulterated and misbranded feeds; provides criminal penalties for violations and authorizes seizures of offending products. (P.L. 59-384).
Review evidence of safety (P.L. 75-717) and effectiveness (P.L. 87-781) before approving an animal drug.
Review safety and effectiveness of animal drugs for intended use, including safety for use in food-producing animals. (P.L. 90-399).
Authorities Added Between 1980 and 2007
Authority for abbreviated applications for generic animal drugs. (P.L. 100-670).
Authority for veterinarians to prescribe, for animals, extra-label uses of certain approved animal and human drugs, under certain conditions. (P.L. 103-396).
Added flexibility in approving new animal drugs, including an amended definition of substantial evidence of effectiveness. Granted authority for the use of veterinary drugs in animal feeds, with veterinary prescription. (P.L. 104-250).
Requirements for facilities that manufacture, process, pack, or hold animal feed for domestic consumption to register and maintain records. (P.L.107-188).
Authority to collect user fees for certain animal drug applications. (P.L. 108-130).
Conditional approval of veterinary drugs for minor uses or minor species, based on demonstration of safety without all necessary effectiveness data. (P.L. 108-282).
Required, for pet foods, the development of ingredient, processing and labeling standards, and a surveillance system to detect disease outbreaks. Required, for both human foods and animal feeds, the establishment of a reportable food registry, and mandatory reporting of instances of tainted foods. (P.L. 110-85).

Devices and Radiological Health[101]

FDA is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer products.[102] There are thousands of types of medical

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[101] This section was prepared by Erin D. Williams, Specialist in Public Health and Bioethics.

[102] For further information, see CRS Report RL32826, *The Medical Device Approval* (continued...)

devices, from heart pacemakers to contact lenses. Radiation-emitting products regulated by the agency include microwave ovens, video display terminals, and medical ultrasound and x-ray machines. FDA reviews requests to research or market medical devices; collects, analyzes, and acts on information about injuries and other experiences in the use of medical devices and radiation-emitting electronic products; sets and enforces good manufacturing practice regulations and performance standards for radiation-emitting electronic products and medical devices; monitors compliance and surveillance programs for medical devices and radiation-emitting electronic products; and provides technical and other nonfinancial assistance to small manufacturers of medical devices. The agency's current activities related to devices and radiological health (DRH) are primarily conducted by its Center for Devices and Radiological Health. As previously noted, CBER, regulates some devices — specifically those associated with blood collection and processing procedures, as well as with cellular therapies (e.g., stem cell treatments).

In FY1980, after adjusting for inflation, FDA's DRH budget was $97,427,000, which supported 1,399 FTEs (see **Figure 9**). At that time, the agency's responsibilities with respect to devices were governed primarily by the Medical Device Amendments of 1976 (MDMA; P.L. 94-295). MDMA was the first major legislation passed to ensure the safety and effectiveness of medical devices, including diagnostic products, before they could be marketed. The amendments required manufacturers to register with FDA and follow quality control procedures in their manufacturing processes. They also required FDA to conduct premarket review of some products, and to generate performance standards that devices had to meet before they could be marketed.

Between FY1980 and FY2007, several major pieces of device legislation were passed (see **Table 6**). Some of these added new types of responsibilities. In 1990, Congress gave FDA the authority to enforce postmarket requirements for devices, to act on postmarket adverse event reports, and to recall unsafe devices (P.L. 101-629). In 1992, Congress gave FDA the authority to require that manufacturers of defective products implement certain consumer accommodations and pursue penalties for postmarket surveillance noncompliance (P.L. 102-300). In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), major FDA reform legislation that tasked the agency with accelerating its premarket review, and regulating unapproved uses of approved devices (P.L. 105-115).

Other legislation contained provisions that could reduce or minimize, rather than simply increase, the regulatory burden on FDA. For example, while the Mammography Quality Standards Act (MQSA) added the responsibility of requiring the agency to certify mammography facilities, it also provided the authority to collect associated certification fees, creating a new revenue stream (P.L. 102-539). MQSA also allowed certain accredited third-parties to conduct inspections in order to relieve FDA of some of that responsibility.

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[102] (...continued)
Process and Related Legislative Issues, by Erin D. Williams.

In 2002, Congress passed the largest revenue-generating, non-appropriations legislation for FDA's DRH-related activities in the 27-year period under examination: the Medical Device User Fee and Modernization Act (MDUFMA; P.L. 107-250).[103] The law gave FDA the authority to collect user fees for premarket device review, creating another significant source of revenue. It also accredited third-parties to conduct inspections, a measure designed to reduce FDA's regulatory burden. To preclude user fees from supplanting direct appropriations, MDUFMA contained a "trigger," requiring a certain amount of DRH-related direct appropriations for the collection of user fees to continue. In 2005, direct appropriations did not meet the trigger amount. Congress subsequently reduced the trigger amount so FDA could continue to collect the user fees (P.L. 109-43).

Between FY1980 and FY2007, congressional appropriations for DRH-related activities generally followed the agency's budget requests. As **Figure 9** indicates, the number of FTEs and budget remained relatively flat through the 1980s. Both then increased in the early 1990s. Beginning in the late 1990s, the budget and FTEs began to track somewhat differently than they had in the past.[104] The flat budget in the late 1990s did not occur with a fairly constant number of FTEs as it had in the 1980s, but rather with a decrease in FTEs. Likewise, the budget increases that have occurred thus far in the 2000s have increased the number of FTEs, but not by as much as with similar budget increases in the early 1990s. Readers should note that the drop in FTEs between FY2006 and FY2007 apparent in **Figure 9** is misleading, as the FTE numbers are based upon a Continuing Resolution (which had no allowance for user fees), while the budget numbers are based upon a cost estimate (which did include user fees).

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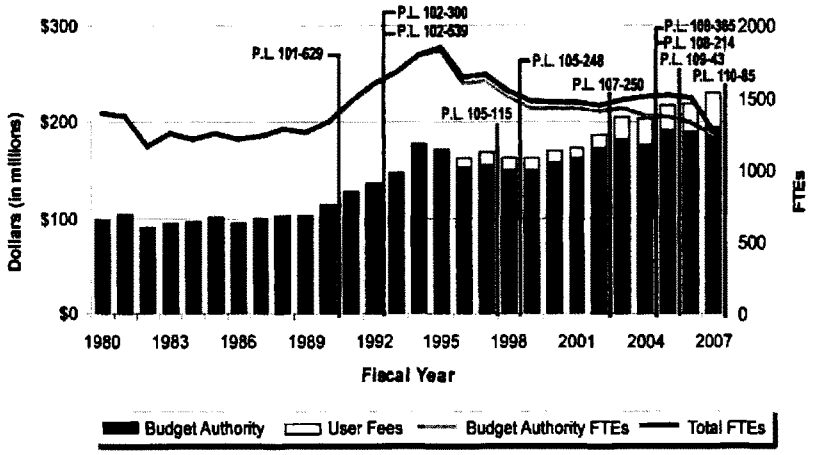
[103] For further information about medical device user fees, see CRS Report RL33981, *Medical Device User Fee and Modernization Act (MDUFMA) Reauthorization*, by Erin D. Williams.

[104] For a general discussion of the relationship between FTE data and budget data, see "Overall FDA Budget" and "FDA Activity-Area Budgets" sections of this report.

Figure 9. Devices and Radiological Health: Budget and FTEs (Constant FY2000 $)



Source: FDA *Justification of Estimates for Appropriations Committees* documents.

Notes: Total FTEs = Budget Authority FTEs + User Fee FTEs. Program Level $ = Budget Authority $ + User Fees $.

The net result of the changes described above was that, over the 27-year period studied, FDA's budget and its number of FTEs dedicated to DRH-related activities increased, although by different amounts. Adjusted for inflation, the total DRH-related budget has increased by 124.5%. The number of FTEs increased by 7.1%. Over the same 27-year period, adjusting for inflation, the budget authority for DRH-related activities increased by 94.2%, while the number of FTEs supported by the budget authority decreased by 5.1%. User fees, which comprised none of the device-related budget in FY1980, comprised 13.5% of it in FY2006. User fee-funded FTEs, which comprised none of the FY1980 budget, comprised 11.3% of the FY2006 budget.

Table 6. Devices and Radiological Health Statutory Authorities in 1980 and 2007

Authorities in 1980
Regulates devices as drugs (Court interpretation of P.L. 75-717).
Enforces label truthfulness, accuracy (P.L. 89-755).
Ensures safety, effectiveness prior to marketing (P.L. 94-295).
Creates, enforces manufacturing quality control procedures (P.L. 94-295).
Maintains manufacturer registry (P.L.94-295).
Authorities Added Between 1980 and 2007
Enforces postmarket requirements (P.L. 101-629).
Receives, acts on postmarket adverse event reports (P.L. 101-629).
Recalls unsafe devices (P.L. 101-629).
Orders certain consumer accommodations by defective product manufacturers (P.L. 102-300).
Pursues penalties for postmarket surveillance noncompliance (P.L. 102-300).
Certifies mammography facilities, collects associated fees (P.L. 102-539, P.L. 105-248, P.L. 108-365).
Accelerates premarket review (P.L. 105-115).
Regulates unapproved uses of approved devices (P.L. 105-115).
Collects user fees for premarket device review (P.L. 107-250, P.L. 108-214, P.L. 109-43).
Accredits third parties to conduct inspections (P.L. 107-250).
Enforces new regulatory requirements for reprocessed single-use devices (P.L. 107-250).

Other Activities and Responsibilities

The above analysis focuses on areas in which FDA has product-specific regulatory responsibilities. However, certain components of FDA's budget and responsibilities do not fall within these categories (e.g., toxicological research, and headquarters and office of the FDA Commissioner) or are funded by components of each area's budget (e.g., FDA's field activities). While an in-depth analysis of these areas is not included in this report, we have provided a brief description of each one below.

Toxicological Research. FDA's activities related to toxicological research are conducted by the National Center for Toxicological Research (NCTR), in Jefferson, AR. NCTR, which was established by Executive Order in 1971, does not have an explicit authority in law, and does not have direct regulatory

responsibilities.[105] NCTR conducts peer-reviewed scientific research and provides expert technical advice and training to support FDA regulatory activities. NCTR uses Interagency Agreements, CRADAs, informal collaborations, and visiting scientists to advance its research activities.

In FY1980, NCTR had 331 FTEs, and a budget of $16,533,000. In FY2006, its budget was $40,739,000, which represented an increase of 6.4% in inflation-adjusted terms from FY1980. During that same period, NCTR's number of FTEs declined by 42.4% to 190.

Headquarters and Office of the Commissioner. The FDA Commissioner has broad authority and responsibility to conduct research to support the agency's mission.[106] The Office of the Commissioner (OC) is made up of several components, including the Ethics Program, Good Clinical Practice Program, History Office, Office of Combination Products, and Office of Crisis Management, among others.[107]

As reported in the FY1982 budget *Justification*, FY1980 funding for the OC was included in FDA's *Program Management* budget line. This line also included funding for the Associate Commissioners and the general management personnel responsible for the central program direction and administrative support functions of the agency. As reported in the FY2008 budget *Justification*, funding for the OC in FY2006 was included under the title *FDA Headquarters and Office of the Commissioner*. It consisted of agency-wide program direction, and administrative services to ensure that FDA's consumer protection efforts were managed and that available resources were put to the most efficient use.

In FY1980, *Program Management* had 553 FTEs and a budget of $42,413,000. In FY2006, the *FDA Headquarters and Office of the Commissioner* budget was $103,886,000, an increase of 5.7% in inflation-adjusted terms. During that same period, the OC's number of FTEs had increased by 21.5% to 672. None of the OC-related activities in FY1980 were funded by user fees. In FY2006 17.5% of the OC-related budget, and 20.8% of the FTEs were funded by user fees.

Field Activities:The Office of Regulatory Affairs. The lead office for FDA's inspection and enforcement activities (which FDA calls "field activities") is the Office of Regulatory Affairs (ORA). ORA is comprised of its Headquarters, the Office of Resource Management, the Office of Regional Operations, the Office of Enforcement, and the Office of Criminal Investigations.[108]

In the FY2008 budget justification, field activities for FY2006 are included as one component of each activity area (drugs, devices, food, etc.). A separate section provides total budget and FTE numbers for field activities. These field activity

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[105] See [http://www.fda.gov/nctr/].

[106] 21 U.S.C. § 393(d)(2)(C).

[107] See [http://www.fda.gov/oc/].

[108] See [http://www.fda.gov/ora/about/default.htm].

numbers are not added in to the total budget under the field activity line. (Otherwise they would be counted twice.) While FDA carried out field activities in FY1980, in the FY1982 budget justification, FTEs and budget numbers for FDA's field activities were not broken out as they were for FY2006. Therefore, there is no FY1980 point of comparison for the FY2006 numbers for field activities.

In FY2006, FDA field activities had a $499,853,000 budget and had 3,460 FTEs. User fee funds accounted for 3.5% of the budget and 1.7% of the FTEs.

Concluding Comments

This report provides information on changes in FDA's resources, both budget and FTEs, as well as the evolution of its statutory responsibilities. Resources and responsibilities are juxtaposed because, as Congress requires more from the agency, it is important to assess whether FDA has the necessary financial resources to meet all those statutory responsibilities. The report is intended to assist Members and their staff in evaluating whether FDA's resources have fallen short, and, if so, how to enhance FDA's performance.

The status of FDA resources and agency performance is important to Congress because each day, FDA-regulated products touch the lives of every American citizen as well as people around the world. As stated previously, about 25% of American consumer dollars are spent on these FDA-regulated products. Among the industries that FDA regulates are some of the most successful and innovative in the U.S. economy. The agency regulates a wide range of products valued at more than $1 trillion. Problems with their safety or effectiveness could affect anyone, as is evident from the following sample of things FDA regulates:

- the calorie and fat content information on food labels;
- permissible and required information in televised prescription drug ads;
- the coloring in foods, medicines, and cosmetics;
- the purity of ingredients in prepared foods — for people and animals;
- inspection requirements for mammography and MRI equipment; and
- antibiotics in the feed fed to animals bred for human consumption.

The data in this report, assembled from the annual material that each President submits to Congress for the next year's appropriation, indicate some year-by-year variation, but mostly illustrate a few trends. For FDA as a whole, comparing FY2006, the most recent year for which we have parallel data sources, to FY1980 yields these inflation-adjusted findings (see **Figure 1**):

FDA Budget:

- almost a doubling of direct congressional appropriations (budget authority);
- more than an 10-fold increase in other funds, mostly user fees;
- resulting in an overall budget in FY2006 almost 2-1/2 times that in FY1980.

FDA FTEs:

- less than a 1% increase in budget authority-funded FTEs;
- an almost fourfold increase in FTEs funded by other sources, mostly user fees;
- resulting in an overall 19% increase from FY1980 to FY2006.

Similar relationships are observed in each of the major activity areas that receive user fees (the Foods program does not have user-fee funds) and are discussed in this report. The human drugs program, along with biologics, was the first to include user fee revenue in its budget and is a good example to illustrate the relationship over time between congressionally appropriated dollars and user fee generated dollars. Again from FY1980 to FY2006, the data show that the human drugs total budget (program level), which included user fee revenue, more than tripled (a 231% increase) although the direct congressional appropriations (budget authority) increased by 78%. The effect of user fees is even more evident in comparing the number of FTEs. The budget authority funded FTEs decreased by 14%, but the overall human drug FTE level increased by 40% because of user fee funding. For the human drug program in FY2006, user fees contributed 46% of the budget and funded 39% of the FTEs.

In general, Congress has either kept direct appropriations in line with inflation (FY1980-FY1988, FY1994-FY1997, and FY2002-2007) or increased them gradually (FY1989-FY1993 and FY1998-FY2001). The exception is FY2002, when Congress increased direct appropriations to FDA by 23%, along with increases to other public safety agencies in response to the attacks of September 11, 2001, and the anthrax mailings soon after.

Congress and various administrations have allowed FDA's research program to diminish and its many data systems are not meeting the agency's needs. The context of this report does not allow a distinction between program decisions made by budget constraints and those made by policy intent.

The focus of this report is the FDA budget. The discussion does not, therefore, explore other possible constraints on FDA's meeting its responsibilities and the public's expectations. Such factors could include the agency's lack of strong advocates, both externally (such as NIH has with its patient advocacy groups) and internally (because of chronic vacancies in key leadership positions, including the Commissioner). Independent of whether the FDA budget is sufficient to cover agency responsibilities is how FDA manages the resources it does have. The influence of non-budgetary factors likely complicates agency actions, though analyzing that is beyond the scope of this report.

From 1980 through 2007, 36 new major statutes were enacted that address FDA activities.[109] This report does not evaluate the impact of individual statutory requirements on the workload and resources needs of the agency. However, an examination of the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85) provides examples of the funding issues discussed in this report. Some news coverage of FDAAA hailed it as "the most sweeping overhaul of the Food and Drug Administration in a decade."[110] In addition to the widely expected reauthorization of drug and device user fees and pediatric drug research incentives, FDAAA, among other things, authorized demonstration grants, including ones for improving pediatric device availability; established mechanisms for public-private partnerships to support FDA's mission to accelerate medical product innovation, translational therapeutics, and enhanced medical product safety; required an expanded clinical trial registry databank; and strengthened FDA's authority to require studies and labeling changes for drugs already on the market.

Implementation of these and other provisions is to involve the development of new regulations and extensive communication with industry and the public. Carrying out these new responsibilities will require time and resources. To fund all these provisions, FDAAA authorized annually an additional $250 million in appropriations and $32 million in user fee revenue.[111] Absent appropriations, these authorizations remain congressional statements of intent.

This report has focused on the presentation of FDA's financial and human resources and statutory responsibilities over time. In presenting that information in context, the report also identifies actions — other than a straightforward increase in direct appropriations — that others have suggested as possible steps to help FDA's budget situation. These propose to:

- Restructure the PDUFA trigger mechanism to minimize its unintended effect of pulling resources from non-PDUFA activities.
- Authorize FDA to bypass the HHS and OMB budget offices in submitting its request for appropriations to Congress.
- Require, in addition to the OMB-processed budget request, that the FDA Commissioner submit to Congress a Professional Judgment budget based on his or her personal expertise and experience.

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[109] This number is held down by the concatenation of many introduced bills into large packages passed as single items. For example, FDAAA of 2007 is counted once although it included the Prescription Drug User Fee Amendments of 2007, the Medical Device User Fees Amendments of 2007, the Pediatric Medical Device Safety and Improvement Act of 2007, the Pediatric Research Equity Act of 2007, and the Best Pharmaceuticals for Children Act of 2007, among many other items.

[110] Drew Armstrong, "Major Elements of the FDA Overhaul," *CQ Weekly: Health*, September 24, 2007, p. 2767.

[111] FDAAA included other provisions that could (but do not necessarily) affect FDA's total program level. These are direction to transfer appropriated funds for specified purposes, authority to assess certain civil penalties, and authority to appropriate funds for certain grants and contracts.

- Move FDA appropriations from the appropriations subcommittees on agriculture to the Labor-HHS subcommittees, which handle most other agencies involved in protecting the public's health.

Appendix. Methodology

This report tracks, as consistently as possible with publicly available material, the FDA budget numbers and employee numbers (FTEs) from FY2007 back to FY1980. The goal was to provide about 25 years of budget and FTE history accompanied by changes in the agency's statutory responsibilities. Only limited budget and FTE data are available from bills and reports of the congressional appropriations committees. Citing constraints on its staff time, FDA indicated that it would only be able to provide data for recent years. Therefore, this report used data prepared annually by FDA for Congress at the beginning of each budget cycle and presented in the *Justification* documents. The *Justifications* are prepared initially by FDA and transmitted through HHS to OMB, often with adjustments made by HHS and OMB. These documents provide detailed budget and FTE data along with an extensive narrative.

Over the years, changes in agency organization, accounting methods, definitions, and other conditions resulted in variations in data presentation in the *Justification* documents. Although some data inconsistencies found in the documents could be explained, other inconsistencies could not. This section of the report provides the basic approach used to calculate historical budget and FTE numbers, highlights inconsistencies among the *Justification* documents, and describes the steps taken to make the data as consistent as possible. There may be additional data inconsistencies that were not found because they were less readily apparent.

The annual *Justification* documents present first the overall FDA information (narrative, and budget and FTE data) followed by information for the various activity areas within the agency. Except as noted below, this report uses data from the *Actuals* column in tables labeled: *All Purpose Table — Total Program Level*; *All Purpose Table — Budget Authority*; and . These tables are found at the beginning of each *Justification* document. The report also uses activity-specific data from similar tables that are included at the beginning of the *Justification's* narrative section on each activity area.

Overall FDA Budget

The FDA's total budget, also called the *program level*, consists of (1) direct congressional appropriations, referred to by FDA as *budget authority*, and (2) funds collected or transferred from other sources, which this report refers to as *other funds* and which FDA lists under *user fees* in recent *Justifications*. Other funds include all of the financial and FTE resources that are available to FDA as itemized in the *Justifications* that are from sources other than direct congressional appropriations. In recent years, the largest component of other funds comes from user fees collected under the authority of the Prescription Drug User Fee Act, the Medical Device User Fee and Modernization Act, and the Animal Drug User Fee Act. Grouped separately in some years' *Justifications* are other fees obtained under the Mammography Quality Standards Act, and fees collected for color certification, export certification, and Freedom of Information Act (FOIA) requests. Additional sources itemized in the *Justifications* include advances and reimbursements; Parklawn Computer Center FTEs; CRADAs; and P.L. 83-480 (Agricultural Trade Development and Assistance

Act of 1954) funds. Note that overall FDA budget authority includes appropriations for both "Salaries and Expenses" and "Buildings and Facilities." (In contrast, as indicated below, activity-area budgets include only "Salary and Expenses.")

Activity Area Budgets

This report follows the order in the FY2008 *Justification* document in presenting information on FDA's five major activity areas: Foods, Human Drugs, Biologics, Animal Drugs and Feeds, and Medical Devices and Radiological Health. For each activity area, the *Justification* provides the amount given by direct congressional appropriations (*budget authority*) and *user fees* (a narrower category than *other funds*), the total of which is the *program level.*

The *Justification* documents do not allocate an amount for Buildings and Facilities to each activity-area. Buildings and Facilities is recorded as a separate line within the overall FDA budget. Activity area amounts in this report's tables and graphs are for Salaries and Expenses.

The report groups remaining FDA activities (Toxicological Research), agency-wide responsibilities (Headquarters and Office of the Commissioner) and expenditures (Rent, Buildings and Facilities) into an "Other Activities" category. **Tables A2 and A3** in the **Appendix** of this report include budget and FTEs for Other Activities within the FDA Total columns, but do not provide a separate Other Activities column. Budget amounts for Other Activities are included in **Figure 1** and **Figure 3**, which present overall FDA data.

Inflation Adjustment

Data in **Table A2** in the **Appendix** are as reported in the *Justifications* and have not been adjusted for inflation. For **Figures 1** and **2** as well as **Figures 4-9**, data have been adjusted for inflation using "Total Non-Defense" deflators from Table 10.1, Gross Domestic Product and Deflators Used in the Historical Tables: 1940-2012, found on pages 192-193 in: Office of Management and Budget, *Historical Tables, Budget of the United States, Fiscal Year 2008.*

Basic Approach

As stated above, this report uses data found in the Actuals column of tables in the *Justification* documents.[112] Budget and FTE information for each activity area found in the overall summary tables at the front of the *Justification* document was compared with information found in the tables within the activity-area sections of the same document for confirmation. When a *Justification* included inconsistent information, *Justification* documents from the preceding and succeeding fiscal years were used to resolve the problem. The steps taken to resolve specific inconsistencies are described below in **Table A1** in the **Appendix**. The reporting format that FDA

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[112] Actuals data for a specific fiscal year can be found in the *Justification* document proposing the agency's budget two fiscal years later. For example, the Actuals data for FY2001 come from the FY2003 *Justification.*

has used within the *Justification* documents to describe both its overall budget and those of its various activities has changed over the past 28 years. The format in this report was kept as consistent as possible with the format found in the FY2008 *Justification*.

Table A1. Actions Taken to Address FDA Budget Data Limitations

Fiscal Year	Limitation in Source Material	Authors' Decision for Report Presentation
1980-1982	FTE and budget amounts for Medical Devices and for Radiological Health were reported separately.	Medical Devices and Radiological Health numbers were added together to create a category consistent with the current *Justification*.
1980-1985	FTE and budget amounts for Foods were separated into three categories: food safety, food labeling or food economics, and cosmetics.	The three categories were added together to create a category consistent with Foods in the current *Justification*.
1980-1985	For FY1980-FY1985, the *Justifications* did not have a summary Budget Authority table that included both Salaries & Expenses and Buildings & Facilities.	Salaries & Expenses and Buildings & Facilities were added together to obtain the budget authority total for the agency.
1980-1985	In contrast to the FY2008 All Purpose tables, the Appropriation Summary tables in the FY1981-FY1986 *Justifications* contained only direct appropriations (budget authority) amounts and did not provide amounts for other funds or program level. The "Total Resources Available" table reported other funds available to FDA. These other funds amounts are reported only for the request year and the preceding year. The table labels did not indicate whether the amounts are estimates or actuals.	For FY1980-FY1985, data from the "Total Resources Table" in the FY1981-FY1986 *Justifications* were used to construct an other funds amount. Other funds and budget authority amounts were added to obtain program level totals.
1983-1987	Human Drugs and Biologics activities merged in 1983 to form the Center for Drugs and Biologics which split in 1987 to form CDER and CBER. *Justifications* reports combined Human Drugs and Biologics FTE and budget amounts for these years.	Tables and figures in this report include footnotes explaining the absence of Biologics data and the jump in Human Drugs resources for these years.
1986-1988	In contrast to the FY2008 All Purpose tables, the Appropriation Summary tables in the FY1988-FY1990 *Justifications* contained only direct appropriations (budget authority) amounts and did not provide amounts for other funds or program level. The "Total Resources Available" table reported other funds available to FDA. These amounts are reported as estimates for the request year and the preceding year and as actuals for the year two years prior to the request. The amount labeled "Total" in the "Total Resources Available" table is equal to program level and the amount labeled "Program Expenses" is equal budget authority. The "Program Expenses" amount is the same as the amount labeled "Total Appropriation" or "Total Obligational Authority" in the FDA Appropriation Summary table.	Amounts labeled Actual in the "Total Resources Available" table were used to calculate other funds. Other funds and budget authority amounts were added to obtain program level totals.

Fiscal Year	Limitation in Source Material	Authors' Decision for Report Presentation
1989-1991	In contrast to the FY2008 All Purpose tables, the Appropriation Summary tables in the FY1991-FY1993 *Justifications* contained only direct appropriations (budget authority) amounts and did not provide amounts for other funds or program level. The "Total Resources Available" table reported other funds available to FDA. These amounts are reported as estimates for the request year and the preceding year and as an actual amount for the year two years prior to the request.	In contrast to above, the amounts labeled Actual in the "Total Resources Available" table were not used to calculate other funds.
1989-1991	In the "Total Resources Available" table, the amount labeled "Total" is equal to program level; however, the amount labeled "Program Expenses" is not equal to budget authority. The "Program Expenses" amount is not the same as the amount labeled "Total Obligational Authority" in the FDA Appropriation Summary table.	Other funds were calculated by subtracting the amount labeled "Total Obligational Authority" in the FDA Appropriation Summary table from the amount labeled "Total" in the "Total Resources Available" table.
1992-1993	The "FDA Budget Authority by Activity" table in the FY1994 and FY1995 *Justifications* contained information similar to that presented in the "All Purpose Tables" of FY2000-FY2008. However, the tables in the FY1994 and FY1995 *Justifications* categorize the information differently: excluding several items from the recent years' "User Fee" category; and omitting a summary equivalent to either "All Purpose — Budget Authority" or "All Purpose — Program Level" as provided in the FY2000-FY2008 *Justifications*.	Individual items from the FY1994 and FY1995 "FDA Budget Authority by Activity" tables were placed in "program level," "budget authority," and "other funds" categories in a manner consistent with their presentation in the "All Purpose Tables" in the FY2000-FY2008 *Justifications*.
1994-1997	The FY1996-FY1999 *Justifications* contained tables at the beginning of the document that, although not labeled as such, have formats and information similar to the "All Purpose Tables" in the FY2000-FY2008 *Justifications*. The tables are titled "FDA Budget Authority by Activity" in the FY1996 and FY1997 *Justifications* and "FDA Congressional Budget Request" in the FY1998 and FY1999 *Justifications*.	The "FDA Budget Authority by Activity" tables and the "FDA Congressional Budget Request" tables were used as the data source.
1993	The overall FDA amount for other funds includes $8,949,000 in Prescription Drug User Fee Act (PDUFA) fees, but a comparable entry is not included in the budget of Human Drugs or Biologics (as is the case for FY1994 through FY2008).	The PDUFA user fee amount was included in the other funds category of the overall FDA budget. In the absence of activity-level data for the PDUFA fees, the PDUFA user fee amount was not included in the user fees category of Human Drugs, Biologics, or any other activity area budget.
2003	The FY2005 *Justification* reported two different overall FDA budget authority amounts in the All Purpose Tables. The overall FDA budget authority is $1,390,071,000 in the All Purpose Table — Budget Authority, and $1,398,350,000 in the All Purpose Table — Total Program Level, a difference of $8,279,000.	Other sections in the FY2005 *Justification* indicated that the table labeled All Purpose Table — Total Program Level likely contained incorrect amounts for the Offices of External Relations and International & Constituent Relations. The overall FDA budget authority amount of $1,390,071,000 from the All Purpose Table — Budget Authority was used.

Fiscal Year	Limitation in Source Material	Authors' Decision for Report Presentation
2004	The FY2006 *Justification* organized data — including Actual data for FY2004 — in a format different than other *Justifications*. That year, activity totals did not include amounts for Office of Regulatory Affairs, but did include rent. In the FY2007 and FY2008 *Justifications*, FDA reverted to the previous format for all activities except for Human Drugs and Biologics.	For Human Drugs and Biologics, FY2004 numbers were reconstructed by adding in Office of Regulatory Affairs amounts and subtracting rent to make them consistent with other years. For the remaining activities (Foods, Animal Drugs and Feeds, and Medical Devices and Radiological Health), amounts from the FY2008 *Justification* were used.
2007	FY2007 ended without passage of an Agriculture appropriations bill. The FY2008 *Justification* used FY2007 amounts from a continuing resolution in effect at the time. Later, a Revised Continuing Appropriations Resolution was enacted. An FDA *Operating Plan* for FY2007 (dated March 2007) reflected the final funding levels under P.L. 110-5, the Revised Continuing Appropriations Resolution, 2007 but did not contain FTE numbers.	The FDA *Operating Plan* was used as the source of budget data. The FY2008 *Justification* was used as the source of FTE data.
2008	Amounts for FY2008 in the FDA FY2008 *Justification* are the President's Budget Request, and, therefore, do not reflect any final action by Congress.	Amounts for FY2008 are labeled "Request" in the **Appendix** tables and are not included in any graphs.

Table A2. FDA Appropriations, Overall and by Major Program, Budget Authority and Other Funding, FY1980 through FY2008, Unadjusted for Inflation

(dollars in thousands)

	FDA			Foods	Human Drugs		Biologics		Animal Drugs & Feeds		Devices & Radiol.	
Fiscal Year	Program Level[a]	Budget Authority	Other Funds	Budget Authority	Budget Authority	User Fees	Budget Authority	User Fees	Budget Authority	User Fees	Budget Authority	User Fees
1980	339,864	324,829	15,035	95,107	72,119	0	22,147	0	23,498	0	49,035	0
1981	346,294	331,420	14,874	92,373	76,476	0	21,638	0	21,000	0	58,218	0
1982	353,861	341,624	12,237	104,253	72,284	0	23,174	0	21,499	0	53,364	0
1983	397,896	391,387	6,509	103,294	108,472	0	—[b]	0	22,011	0	58,836	0
1984	400,502	392,649	7,853	116,000	114,335	0	—[b]	0	23,913	0	62,568	0
1985	423,935	414,345	9,590	110,541	130,996	0	—[b]	0	23,427	0	67,263	0
1986	412,361	404,361	8,000	109,753	129,609	0	—[b]	0	22,778	0	65,561	0
1987	457,351	447,144	10,207	120,449	151,642	0	—[b]	0	24,866	0	70,972	0
1988	486,051	477,504	8,547	126,401	117,132	0	51,379	0	25,406	0	74,911	0
1989	552,447	542,343	10,104	141,211	131,215	0	60,471	0	24,452	0	78,457	0
1990	611,551	600,979	10,572	161,082	146,519	0	73,241	0	30,670	0	89,365	0
1991	707,467	688,392	19,075	183,899	176,402	0	83,086	0	35,256	0	104,778	0
1992	777,850	761,830	16,020	206,304	198,538	0	90,531	0	39,000	0	116,731	0
1993	824,105	796,869	27,236	204,690	211,647	0	98,281	0	38,017	0	129,025	0
1994	920,745	875,968	44,777	213,014	214,855	23,108	110,748	16,843	40,318	0	159,359	0
1995	948,268	869,230	79,038	216,398	217,940	48,413	104,113	25,651	41,684	0	157,021	0
1996	988,341	889,527	98,814	200,941	202,024	50,863	87,315	29,991	36,814	0	143,717	8,557
1997	997,005	880,743	116,262	191,183	201,079	53,336	96,256	26,384	36,216	0	147,372	12,449
1998	1,050,299	931,883	118,416	206,249	199,579	63,069	95,479	27,533	41,354	0	144,329	11,376
1999	1,129,993	985,279	144,714	235,168	200,423	77,876	95,023	29,342	43,253	0	145,790	13,218
2000	1,213,983	1,048,149	165,834	279,704	215,538	95,696	106,133	34,584	49,593	0	157,656	12,601
2001	1,278,147	1,099,311	178,836	287,504	218,515	103,965	108,303	38,927	64,070	0	165,306	12,259

	FDA			Foods	Human Drugs		Biologics		Animal Drugs & Feeds		Devices & Radiol.	
Fiscal Year	Program Level[a]	Budget Authority	Other Funds	Budget Authority	Budget Authority	User Fees	Budget Authority	User Fees	Budget Authority	User Fees	Budget Authority	User Fees
2002	1,536,959	1,354,366	182,593	393,256	254,700	109,644	138,605	39,237	85,643	0	179,962	13,695
2003	1,627,656	1,390,071	237,585	406,824	274,073	129,775	145,318	48,118	87,659	0	193,350	23,935
2004	1,678,904	1,401,214	277,690	407,052	292,118	167,474	122,354	44,662	83,458	983	191,143	30,363
2005	1,777,474	1,452,274	325,200	435,517	291,484	190,650	123,109	47,575	90,484	7,538	214,962	29,320
2006	1,862,694	1,493,580	369,114	438,721	297,715	211,190	138,518	59,191	89,580	8,264	220,563	34,478
2007	2,007,727	1,574,194	433,533	457,105	315,138	255,238	144,547	65,738	94,749	9,537	230,710	42,237
2008[c]	2,084,649	1,640,659	443,990	466,726	324,438	232,358	155,073	60,762	94,809	11,523	240,122	45,254

Sources: FDA *Justification of Estimates for Appropriations Committees* documents.

Notes: FDA's foods program budget does not include user fee revenue. Devices and Radiological Products were added for 1980, 1981, and 1982. User Fees in 1992 are Revolving Fund — Certification Fees. User Fees in 1993 are PDUFA plus Revolving Fund — Certification Fees. Unclear how 1993 PDUFA user fees were allocated.
The FY2007 is Operating Plan for 2007 (Dated March 2007) reflecting funding levels under P.L. 110-5.

a. Total program level = budget authority (direct appropriations) + other funding (e.g., user fees).
b. For FY1983 through FY1987, FDA managed Biologics activities and Human Drugs activities in one Center. The *Justifications* for those years provide only combined dollar amounts which are included in Human Drugs and not in Biologics.
c. FY2008 amounts are the Administration request levels.

Table A3. Full-time Equivalents, Overall and by Major Program, Budget Authority-Funded and Other-Funded, FY1980 through FY2008

Year	FDA FTEs			Food FTEs	Human Drugs FTEs			Biologics FTEs			Animal Drugs & Feeds FTEs			Devices & Radiological Health FTEs		
	BA	Other Funds	Total	Total	BA	User Fee	Total	BA	User Fee	Total	BA	User Fee	Total	BA	User Fee	Total
1980	7,816	366	8,182	2,408	2,102	0	2,102	507	0	507	516	0	516	1,399	0	1,399
1981	7,558	374	7,932	2,319	2,023	0	2,023	490	0	490	499	0	499	1,375	0	1,375
1982	7,011	374	7,385	2,496	1,703	0	1,703	410	0	410	446	0	446	1,161	0	1,161
1983	7,122	184	7,306	2,257	2,356	0	2,356	—[a]	—[a]	—[a]	450	0	450	1,258	0	1,258
1984	7,089	188	7,277	2,396	2,228	0	2,228	—[a]	—[a]	—[a]	458	0	458	1,211	0	1,211
1985	7,024	188	7,212	2,164	2,446	0	2,446	—[a]	—[a]	—[a]	426	0	426	1,259	0	1,259
1986	6,832	169	7,001	2,091	2,406	0	2,406	—[a]	—[a]	—[a]	441	0	441	1,217	0	1,217
1987	6,794	169	6,963	2,071	2,423	0	2,423	—[a]	—[a]	—[a]	441	0	441	1,238	0	1,238
1988	7,039	171	7,210	2,146	1,942	0	1,942	584	0	584	441	0	441	1,282	0	1,282
1989	7,228	170	7,398	2,377	1,913	0	1,913	674	0	674	414	0	414	1,263	0	1,263
1990	7,629	185	7,814	2,475	2,026	0	2,026	775	0	775	438	0	438	1,332	0	1,332
1991	8,267	183	8,450	2,637	2,263	0	2,263	824	0	824	483	0	483	1,482	0	1,482
1992	8,792	302	9,094	2,793	2,390	0	2,390	898	0	898	506	0	506	1,604	0	1,604
1993	8,939	200	9,139	2,695	2,449	0	2,449	969	0	969	485	0	485	1,683	0	1,683
1994	8,963	389	9,352	2,675	2,412	78	2,490	977	126	1,103	495	0	495	1,799	0	1,799
1995	8,811	453	9,264	2,590	2,278	295	2,573	954	158	1,112	468	0	468	1,831	0	1,831
1996	8,487	685	9,172	2,348	2,108	351	2,459	804	206	1,010	403	0	403	1,603	43	1,646
1997	8,354	817	9,171	2,226	2,069	446	2,515	861	209	1,070	382	0	382	1,619	48	1,667
1998	8,083	821	8,904	2,239	1,959	470	2,429	841	186	1,027	391	0	391	1,507	48	1,555

Year	FDA FTEs			Food FTEs	Human Drugs FTEs			Biologics FTEs			Animal Drugs & Feeds FTEs			Devices & Radiological Health FTEs		
	BA	Other Funds	Total	Total	BA	User Fee	Total	BA	User Fee	Total	BA	User Fee	Total	BA	User Fee	Total
1999	7,851	1,059	8,910	2,339	1,846	610	2,456	791	198	989	393	0	393	1,432	48	1,480
2000	7,728	1,102	8,830	2,386	1,838	671	2,509	780	211	991	406	0	406	1,426	46	1,472
2001	7,805	1,184	8,989	2,445	1,824	711	2,535	786	255	1,041	442	0	442	1,428	45	1,473
2002	8,311	1,157	9,468	2,734	1,817	700	2,517	894	242	1,136	570	0	570	1,407	47	1,454
2003	8,940	1,317	10,257	3,167	1,920	776	2,696	947	282	1,229	596	0	596	1,432	53	1,485
2004	8,567	1,574	10,141	3,082	1,977	972	2,949	792	246	1,038	592	3	595	1,376	139	1,515
2005	8,181	1,729	9,910	2,943	1,837	1,081	2,918	768	273	1,041	571	39	610	1,367	149	1,516
2006	7,893	1,805	9,698	2,774	1,801	1,146	2,947	730	249	979	538	54	592	1,328	170	1,498
2007	7,510	1,529	9,039	2,613	1,703	1,122	2,825	776	215	991	502	0	502	1,235	34	1,269
2008[b]	7,987	1,902	9,889	2,702	1,826	1,205	3,031	838	263	1,101	561	58	619	1,359	180	1,539

Source: FDA *Justification of Estimates for Appropriations Committees* documents.

Note: FDA's foods program budget does not include user fee revenue.

a. For FY1983 through FY1987, FDA managed Biologics activities and Human Drugs activities in one Center. The *Justifications* for those years provide only combined FTEs which are included in Human Drugs and not in Biologics.

b. FY2008 based on Administration request.

Table A4. Selected Public Laws Since 1848 Significantly Affecting FDA Activities

Public Law	Title and Brief Description of Law	Activity*
	Drug Importation Act (An Act to Prevent the Importation of Adulterated and Spurious Drugs and Medicines, 30th Congress, Session 1, Chpt. 70; 1848; 237-239) required the Department of the Treasury (U.S. Customs Service) to inspect drugs from abroad for quality, purity, and fitness for medical purposes.	D
59-384	**Pure Food and Drug Act of 1906**, administered by the then-USDA Bureau of Chemistry, required the food division to prohibit interstate commerce in food, drink, and drug products that were adulterated and misbranded. It provided criminal penalties for violations and also authorized the seizure of offending products. It defined *drug* (substance intended to be used for the cure, mitigation, or prevention of disease of either man or other animals), *adulteration* (differing from established standards of strength, quality, or purity), and *misbranding* (contents not as labeled, including quantities of alcohol and certain narcotics). The act also referred to drug descriptions in the *United States Pharmacopeia* and the *National Formulary* as referents for judging purity and label accuracy. Regarding food, misbranding was confined to making false or misleading statements on the package or label, and adulteration was limited because no standards existed, so generalities described the intermixture or substitution of substances that reduced quality, the concealment of damage or inferiority, the addition of deleterious ingredients, and the use of spoiled products.	F, D, A
62-301	**Sherley Amendment of 1912** expanded the definition of misbranding to include false statements of curative or therapeutic effect.	D
63-223	**Harrison Narcotics Act of 1914** required "every person who produces, imports, manufactures, compounds, deals in, dispenses, sells, distributes, or gives away opium" or certain other narcotics to register with the collectors of internal revenue, pay a special tax, and keep records. It also required a written prescription (on a form provided by the Commissioner of Internal Revenue) for the dispensing of quantities of those narcotics above the amounts specified.	D
67-513	**Filled Milk Act of 1923** defined filled milk as any milk, cream or skimmed milk, regardless of its form, to which is added, blended, or compounded any fat or oil other than milk fat so that the resulting product is an imitation of milk, cream, or skimmed milk. The act declared that filled milk is an adulterated article or food, injurious to the public health and that its sale constituted a fraud upon the public.	F
67-625	**Import Milk Act of 1927** regulated the importation of milk and cream into the United States for the purpose of promoting the U.S. dairy industry and protecting public health. The act required that a valid permit be obtained from the Secretary of Health and Human Services for milk and cream to be imported into the country.	F
75-447	**Wheeler-Lea Act of 1938** assigned to the Federal Trade Commission oversight of advertising associated with products otherwise regulated by FDA.	D
75-717	**Federal Food, Drug, and Cosmetic Act of 1938** is considered the primary foundation of current food and drug law on which subsequent statutes have been added. The food provisions specifically required FDA to promulgate definitions and standards for foods and informative labeling. In addition, it prohibited false advertising and the addition of substances that would render the food adulterated, unless safe tolerance levels were provided for such substances. The drug provisions required that drugs be proven safe before they could be sold in interstate commerce; prohibited the adulteration and misbranding of a drug, the introduction of such a drug into interstate commerce, and the receipt of such a drug; increased penalties if misbranding involved an intent to defraud; required records of shipments; authorized inspection of a facility that manufactures, processes, packs, or holds drugs (and other FDA-regulated products), including its equipment, materials, containers, and labeling; and required regulations for the certification of batches of color additives. The act expanded the definition of *drug* beyond substances intended to be used in the cure, mitigation, and prevention of disease to	F, D, B, A, D&R

Public Law	Title and Brief Description of Law	Activity[a]
	include articles intended for use in the diagnosis and treatment of disease; and further expanded the definition to include "articles ... intended to affect the structure of any function of the body of man or other animals." It expanded the scope of *misbranding*, including requirements for labeling, packaging, quantity, directions for use, and warnings, among others. The courts have allowed FDA to apply these drug regulations to medical devices.	
77-366	**Insulin Amendment of 1941** required that the Federal Security Administrator (FSA; from 1940 to 1953, FDA resided in the Federal Security Agency) provide for the testing and certification of each batch of insulin for strength, quality, and purity. The law also directed the Administrator to promulgate regulations covering, among other things, standards and tests.	D
78-410	**Public Health Service Act of 1944** required individuals or companies who manufacture biologics that enter into interstate commerce to hold a license for such products. Authorizes the inspection of manufacturing establishments involved in the preparation of biological products, and the recall of products without a license or that present an imminent hazard to the public health; and provides civil and criminal penalties for violations.	B
79-139	**Penicillin Amendment of 1945** required that the FSA provide for the certification of each batch of penicillin for strength, quality, and purity; and that the FSA promulgate regulations.	D
82-215	**Durham-Humphrey Amendment of 1951** restricted to *prescription only* the sale of a drug that is habit-forming or that is not safe for use except under the supervision of a licensed practitioner. It also authorized the Secretary to remove the prescription requirement from a drug if the requirement is not necessary for the protection of public health.	D
83-217	**Factory Inspection Amendment of 1953** expanded the FFDCA section on factory inspection to require that the inspector give the owner and send to the Secretary a written report of unsatisfactory conditions. The amended version of the section no longer required an owner's permission to enter the facility for inspection, which the 1938 law had included.	D
83-518	**Miller Pesticide Amendment of 1954** provided FDA with authority to establish tolerances for pesticides on agricultural commodities.	F
85-929	**Food Additive Amendments of 1958** established a premarket approval system for new food ingredients and many food contact substances.	F, A
86-618	**Color Additive Amendments of 1960** established a premarket approval system for colors used in food, drugs and cosmetics. Required that the Secretary promulgate regulations for the listing of color additives in or on food, drugs, and cosmetics based on conditions, uses, and labeling to assure safe use.	F, D
87-781	**Kefauver-Harris Drug Amendments of 1962** to the FFDCA required that drugmakers prove the effectiveness of their products as well as safety. The law also reassigned the authority to regulate prescription drug advertising from the Federal Trade Commission to the Food and Drug Administration and included expanded FDA authority to all antibiotics.	D
89-74	**Drug Abuse Control Amendments of 1965** restricted the manufacture, compounding, and processing of depressant and stimulant drugs; required that manufacturers, sellers, and others keep records and allow the Secretary to verify records and inspect facilities. The law limited the number of prescription refills, and authorized the Secretary to exempt a drug and to appoint expert advisory committees under certain circumstances; and it specified penalties.	D
89-755	**Fair Packaging and Labeling Act of 1966** required any packaged consumer product in commerce to display a legible, prominent label that states the identity of the contents, quantity, and name and place of the manufacturer, packer, or distributor. The act also authorized FDA to adopt regulations to prevent the non-functional fill of packages. It designated the HHS Secretary to promulgate regulations for food, drugs, devices, and cosmetics.	F, D, D&R
90-399	**Animal Drug Amendments of 1968** established a new section 512 of the FFDCA to apply specifically to the approval of animal drugs, extended the requirements for FDA to review the safety and effectiveness of animal drugs for intended use, and included a review of safety for their use in food-	A

Public Law	Title and Brief Description of Law	Activity[a]
	producing animals.	
91-513	**Controlled Substances Act (part of the Comprehensive Drug Abuse Prevention and Control Act of 1970)** authorized the Attorney General (AG) to categorize certain drugs across five schedules based on their potential for abuse, potential for physical or psychological dependence, and accepted medical uses. Required that the AG request scientific advice from the HHS Secretary. Required the Secretary (via FDA) to notify the AG when a submitted new drug application involves a drug with an abuse potential.	D
91-597	**Egg Products Inspection Act of 1970** required FDA to inspect certain egg products and established uniform standards for grading eggs. In addition, the agency is responsible for the regulation of processing and distribution of eggs and egg products to prevent the movement or sale for use in human food of eggs and egg products that are adulterated or misbranded.	F
94-278	**Vitamin-Mineral Amendment of 1976** limited FDA's authority to regulate the composition and promotion of dietary supplements, marking a rejection of the agency's decade-long effort to control high potency nutritional products and health food.	F
94-295	**Medical Device Amendments of 1976** This law was the first major legislation passed to ensure safety and effectiveness of medical devices, including diagnostic products, before they could be marketed. The amendments required manufacturers to register with FDA and follow quality control procedures in their manufacturing processes. Some products were required to undergo premarket review by FDA, while others had to meet performance standards before marketing.	D&R
96-359	**Infant Formula Act of 1980** enlarged FDA's authority over infant formulas by establishing reporting requirements, quality control procedures, recall requirements, exemptions, and labeling and nutrient requirements. The Anti-Drug Abuse Act of 1986 (P.L. 99-570) added additional requirements for infant formula recalls and new microbiological testing and record retention requirements.	F
97-414	**Orphan Drug Act of 1983** provided incentives for pharmaceutical manufacturers to develop drugs, biotechnology products, and medical devices for the treatment of rare diseases and conditions.	D
98-127	**Federal Anti-Tampering Act of 1983** maked it a crime to tamper with packaged consumer products and authorized the FDA to investigate violations.	F, D, B, A, D&R
98-417	**Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act)** changed patent law to allow earlier market entry of generic drugs, while also extending brand-name patent terms to reflect regulatory delays during FDA approval.	D
100-293	**Prescription Drug Marketing Act of 1987** banned the sale, trade, and purchase of drug samples; mandated storage, handling, and accounting standards for drug samples; and required that drug wholesalers be licensed by the states.	D
100-670	**Generic Animal Drug and Patent Term Restoration Act of 1988** amended the FFDCA to authorize abbreviated applications for the approval of a new animal drug.	A
101-500	**Sanitary Food Transport Act of 1990** was primarily focused on the transportation of food under the jurisdiction of the Secretary of the Department of Transportation (DOT). The act required DOT to work with other departments, including HHS, to provide assistance in food transportation inspections.	F, A
101-535	**Nutrition Labeling and Education Act of 1990** provided authority for the agency to mandate nutrition labels on most food products and allow nutrient content and health claims. Most state and local requirements for labeling were preempted, giving FDA responsibility for regulating all aspects of nutrition labeling information.	F

Public Law	Title and Brief Description of Law	Activity[a]
101-629	**Safe Medical Devices Act of 1990** established postmarket requirements for medical devices, and required facilities that use medical devices to report to FDA any incident that suggested that a medical device could have caused or contributed to the death, serious illness, or injury of a patient. The act authorized FDA to carry out certain enforcement actions, such as device product recalls, for products that did not comply with the law.	D&R
102-282	**Generic Drug Enforcement Act of 1992** imposed debarment and other penalties for illegal acts involving abbreviated drug applications (i.e., for generic drugs).	D
102-300	**Medical Device Amendments of 1992** authorized FDA to order a manufacturer, importer, or distributor to repair or replace a device, or refund the purchase price to the customer, when the device was improperly designed or manufactured; revised reporting requirements. It made failure to comply with a requirement imposed by provisions of the FFDCA concerning postmarket surveillance a prohibited act subject to criminal and civil penalties, and deemed any device product misbranded if there was a failure or refusal to comply with postmarket surveillance requirements.	D&R, B
102-539	**Mammography Quality Standards Act of 1992** amended the Public Health Service Act to require certification in order for a facility to perform or interpret mammograms, inspect equipment, or provide for the processing of mammography film. It mandated standards to assure the safety and accuracy of mammograms, and directed the Secretary to conduct annual inspections of certified facilities. It also mandated fees to cover the costs of inspections. This law was amended and reauthorized by the Mammography Quality Standards Reauthorization Act of 1998 (P.L. 105-248) and the Mammography Quality Standards Reauthorization Act of 2004 (P.L. 108-365).	D&R
102-571	**Prescription Drug User Fee Act of 1992 (PDUFA)** authorized, for five years, FDA to assess and collect fees from the pharmaceutical manufacturers and to use the resulting revenue to support its review of new drug and biologics applications.	D, B
103-396	**Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA)** allowed veterinarians to prescribe for animals, under certain conditions, certain approved animal and human drugs for use in a manner that is not in accordance with the approved label directions (extra-label use). Among other requirements, any extra-label use must be by or on the order of a veterinarian within the context of a veterinarian-client-patient relationship and must not result in violative residues in food-producing animals.	A
103-417	**Dietary Supplement Health and Education Act of 1994** provided specific authority for the agency to regulate supplements, by defining the products, and placing the burden of proof on FDA to demonstrate that a supplement already on the market is unsafe and should be removed. The law allows third party literature on the use of supplements and statements of nutritional support to be exempt from labeling regulations. Supplements are required to provide ingredient and nutrition labeling information. The law required manufacturers of a new dietary ingredient entering the market to petition FDA with evidence of safety under its intended conditions of use. Finally, good manufacturing practices (GMPs) were to be promulgated by the agency; so far FDA has only proposed, but not finalized the GMPs for supplements.	F
104-170	**Food Quality Protection Act of 1996** affected pesticide provisions of both the FDA's FFDCA and the Environmental Protection Agency's Federal Insecticide, Fungicide, and Rodenticide Act. Under FFDCA, FQPA established a single, health-based standard for all pesticides in all foods, eliminating the longstanding problems posed by multiple standards for pesticides in raw and processed foods. It also provided special safety provisions for infants and children, limited consideration of benefits, and allowed FDA to impose civil penalties for tolerance violations. The act required tolerance level reevaluation in ten years, and added provisions for endocrine testing, the right to know, and required national uniformity of tolerances, unless a state petitions for an exception.	F
104-250	**Animal Drug Availability Act of 1996** amended the FFDCA to grant FDA more flexibility in evaluating and approving new animal drugs, by amending	A

Public Law	Title and Brief Description of Law	Activity[a]
	the definition of substantial evidence of effectiveness. Among other provisions, the law also permitted the use of veterinary drugs in animal feeds, with a veterinary prescription.	
105-115	**Food and Drug Administration Modernization Act of 1997 (FDAMA)** reauthorized the prescription drug user fee program for five years; provided fast track approval consideration to drugs that would treat life-threatening conditions; eased certain requirements for drug approval; required guidance documents to streamline the drug review process and provide a means for resolving controversial scientific issues; allowed expanded patient access to investigational therapies; encouraged international harmonization agreements and established national uniformity in the regulation of nonprescription drugs and cosmetics; and required that FDA conduct its regulatory functions under a mission statement that will obligate it to maintain a public health protection role while seeking to expedite the marketing of regulated products. FDAMA contained a limited number of provisions specific to food regulations. It eliminated the requirement of FDA's premarket approval for most packaging and other substances that come in contact with food and may migrate into the food product. Instead, the law established a process for the manufacturer to notify the agency about its intention to use certain food contact substances and unless FDA objected within 120 days, the manufacturer could proceed to market the new product. Implementation of the notification process is contingent on additional appropriations to cover its cost to the agency. Another food provision expanded procedures under which FDA can authorize health claims and nutrition content claims without reducing the statutory standard. Medical device provisions included measures to accelerate premarket review of devices and to regulate company advertising of unapproved uses of approved devices.	F, D, B, A, D&R
105-115	**Better Pharmaceuticals for Children Act (part of FDAMA)** authorized, for five years, FDA to grant a drug manufacturer an additional six months of marketing exclusivity in exchange for completing FDA-requested studies of the use of a drug in children.	D
105-248	**Mammography Quality Standards Reauthorization Act of 1998** reauthorized provisions relating to the certification of mammography facilities, including standards for accreditation bodies, inspection of facilities, and civil money penalties for failure to comply with standards.	D&R
106-387	**Medicine Equity and Drug Safety Act of 2000 (MEDS Act, part of the FY2001 Agriculture appropriations bill)** authorized a five-year program allowing pharmacists and drug wholesalers to import lower-priced prescription drugs from specific countries. The law required that the Secretary, before implementing the program, demonstrate that it would pose no additional risk to the public's health and safety, and would result in a significant reduction in the cost of covered products to the American consumer. [Never implemented.]	D
107-109	**Best Pharmaceuticals for Children Act of 2002** renewed the agency's authority (from FDAMA) to give an additional six-month period of marketing exclusivity to a manufacturer in return for FDA-requested pediatric use studies and reports. The act also added provisions to encourage pediatric research in products that are no longer covered by patent or other marketing exclusivity agreements, and in products for which a patent-holding manufacturer declined to conduct an FDA-requested study.	D
107-188	**Public Health Security and Bioterrorism Preparedness and Response Act of 2002** required all domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States to register and maintain records for FDA inspection when it reasonably believed a product to be adulterated, or presenting a threat of serious adverse health consequences or death to humans or animals. The act also required prior notice to FDA of products being imported into the United States and provided the agency with administrative detention authority and penalties where there is credible evidence that a product presents a threat of serious adverse health consequences or death to humans or animals. Reauthorized the prescription drug user fee program.	F, D, B, A, D&R

Public Law	Title and Brief Description of Law	Activity[a]
107-250	**Medical Device User Fee and Modernization Act of 2002** amended the FFDCA to enact three significant provisions for medical devices: (1) it established user fees for premarket reviews of devices; (2) it allowed establishment inspections to be conducted by accredited persons (third parties); and (3) it instituted new regulatory requirements for reprocessed single-use devices. It was modified by the Medical Device Technical Corrections Act (P.L. 108-214), and the Medical Device User Fee Stabilization Act of 2005 (P.L. 109-43).	D&R, B
108-130	**Animal Drug User Fee Act of 2003 (ADUFA)** amended the FFDCA, authorizing FDA to collect fees for certain animal drug applications, and for the establishments, products, and sponsors associated with these and previously approved animal drug applications, in support of the review of animal drugs. The law is similar to PDUFA and MDUFMA. ADUFA program authority sunsets after October 1, 2008.	A
108-155	**Pediatric Research Equity Act of 2003** required a manufacturer to submit, along with an application to market a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration for a drug or biologic, a pediatric assessment of the safety and effectiveness (and data to support dosing and administration) of the product for the claimed indications in all relevant pediatric subpopulations; and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The act also authorized the Secretary to require the manufacturer of an approved drug or licensed biologic to submit a pediatric assessment in situations in which not having pediatric use information on the label could pose significant risks.	D, B
108-173	**Medicare Prescription Drug Improvement and Modernization Act of 2003** replaced the drug importation provisions from the MEDS Act with a similar section that also required the Secretary's certification of safety and cost savings; it also directed the HHS Secretary to study and report to Congress on the importation of prescription drugs into the United States. The act also required the Secretary to study how to use technologies to provide prescription drug information to the blind and visually impaired.	D
108-214	**Medical Devices Technical Corrections Act** amended the FFDCA (as amended by the Medical Device User Fee and Modernization Act of 2002) to revise provisions concerning medical devices user fees, third-party inspection and accreditation requirements, and electronic labeling.	D&R, B
108-276	**Project BioShield Act of 2004** authorized FDA to expedite its review procedures to enable rapid distribution of treatments as countermeasures to chemical, biological, and nuclear agents that may be used in a terrorist attack, among other provisions.	D, B
108-282	**Food Allergen Labeling and Consumer Protection Act of 2004** required that a specific statement about the most frequent allergens appear on a food product when any of those allergens are present in a food.	F
108-282	**Minor Use and Minor Species Animal Health Act of 2004 (MUMS)** enhanced the availability of drugs to treat minor animal species, and uncommon diseases in major animal species (cattle, swine, chickens, turkeys, horses, dogs, and cats). The law amended the FFDCA to authorize: (1) conditional approval, which allows the sponsor to make a drug available before collecting all necessary effectiveness data, but after proving the drug is safe; (2) addition of the drug to an index of legally marketed unapproved new animal drugs, when the potential market for a drug is too small to support the costs of the approval process even under a conditional approval; and (3) certain incentives for approval (similar to the human Orphan Drug Act), including grants to support safety and effectiveness testing, and seven years of marketing exclusivity.	A
108-358	**Anabolic Steroid Control Act of 2004** reclassified certain drug and dietary supplement products as controlled substances. Included were any products that contained an anabolic steroid or a precursor to that steroid that would be converted in the body.	F
108-365	**Mammography Quality Standards Reauthorization Act of 2004** amended the PHSA to authorize the HHS Secretary to issue a temporary renewal certificate or a limited provisional certificate to a mammography facility seeking reaccreditation in certain circumstances; made certain requirements of the	D&R

Public Law	Title and Brief Description of Law	Activity[a]
	Secretary regarding the National Mammography Quality Assurance Advisory Committee; and authorized related appropriations through FY2007.	
109-43	**Medical Device User Fee Stabilization Act of 2005** amended the FFDCA to adjust medical device user fees, repeal fee revenue target amounts, eliminate fee setting adjustments, and deem as branded any reprocessed single use device unless it identifies the manufacturer.	D&R, B
109-462	**Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006** amended FFDCA to require a manufacturer, packer, or distributor whose name appears on the label of a nonprescription drug or supplement to report to FDA, within 15 business days, any serious adverse event associated with use of the product, report any followup information, and maintain and permit inspection of related records.	F
110-85	**FDA Amendments Act of 2007** reauthorized existing FDA programs (prescription drug and medical device user fees, pediatric research incentives); and expanded the agency's authority to regulate the safety of food (including animal feeds), prescription drugs, biologics, and medical devices. Among the new authorities were those concerning clinical trial databases, civil monetary penalties, a new nonprofit entity to support the FDA mission, and information to be made available to the public.	F, D, B, A, D&R

a. F = Foods; D = Human Drugs; B = Biologics; A = Animal Drugs and Feeds; D&R = Devices and Radiological Health.

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January 22, 2008

Dr. Andrew Von Eschenbach
Commissioner, Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dr. Von Eschenbach:

I am sorry you could not be present for the presentation of the Subcommittee Report on Science in the FDA which was made to the Science Advisory Board by Gail Cassell and a number of other Committee members. The Report was extremely well received by the SAB. It was unanimously accepted and the Subcommittee was dissolved.

In her transmission motion, Dr. Cassell did indicate that the SAB should conduct additional studies of some components of the FDA in follow-up to the Report. The SAB concurred in this recommendation.

Comments made by SAB members indicated that they believed the Report to be a landmark study which should be widely discussed. I enclose a copy of the bound of the Report for your review, although I presume that you have access to the Report which was submitted to the Advisory Board.

Best wishes,

Kenneth I. Shine, M.D.
Executive Vice Chancellor for Health Affairs, The University of Texas System

KIS/tlw

xc: Dr. Gail Cassell

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January 23, 2008

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Dr. Gail Cassell
Eli Lilly and Company
940 S. East Street, Dock 88
DC 1053
Indianapolis, IN 46225

Dear Gail:

Thank you again for your extraordinary leadership of the Subcommittee to examine the Science Programs of the FDA. The Science Advisory Board of the FDA, which is the advisory to the Commissioner, unanimously accepted your report at its meeting of December 3, 2007.

The Board believed that the Subcommittee had completed its work and approved a motion to dissolve the Subcommittee. It approved your motion to do some follow-up work on areas in which the Subcommittee could not complete an in-depth analysis but that these further reviews would be would be conducted by the SAB independent of your Subcommittee report. However the discussion indicated that the Board clearly wished to have your report widely available and understood by the various constituencies.

The Board acknowledged your extraordinary efforts and those of your colleagues and expressed its appreciation for your completion on an outstanding product.

Since the Scientific Advisory Board is advisory to the Commissioner, the Board assumed that your report would be made available to him.

Thank you again for your extraordinary efforts.

Yours truly,

Kenneth I. Shine, M.D.
Executive Vice Chancellor for Health Affairs, The University of Texas System

Immediate Past Chairman of the Scientific Advisory Board

KIS/tlw

The New York Times
nytimes.com

December 1, 2007

Advisers Say F.D.A.'s Flaws Put Lives at Risk

By GARDINER HARRIS

Correction Appended

WASHINGTON, Nov. 30 — The nation's food supply is at risk, its drugs are potentially dangerous and its citizens' lives are at stake because the Food and Drug Administration is desperately short of money and poorly organized, according to an alarming report by agency advisers.

The report, made public on Thursday, is the latest and perhaps most far-reaching in a string of outside assessments that have concluded that the F.D.A. is poorly equipped to protect the public health.

It was written by three members of the F.D.A. Science Board, an advisory panel that reports directly to the agency's commissioner, Dr. Andrew C. von Eschenbach. The three authors in turn had 30 scientific advisers.

The report concludes that over the last two decades, the agency's public health responsibilities have soared while its appropriations have barely budged. The result is that the F.D.A. is falling farther and farther behind in carrying out its responsibilities and understanding the science it needs to do its many jobs.

"F.D.A.'s inability to keep up with scientific advances means that American lives are at risk," the report stated.

Sandy Walsh of the F.D.A. said the agency "values the evaluation done by the subcommittee members and the scientific experts that were consulted" but would not comment further.

Barbara J. McNeil, a professor of health care policy at Harvard Medical School and one of the report's authors, said she was stunned at the agency's sorry state.

"This was the first time that a group of people got together and really looked at all the areas that the F.D.A. has to cover," Dr. McNeil said. "We were shocked at the scope of its responsibilities, we were shocked at how little its resources have increased, and we were surprised at the conditions those in the F.D.A. had to work under."

The report notes that the agency's computer systems are aging and prone to breakdowns, "most recently during an E. coli food contamination investigation."

"Reports of product dangers are not rapidly compared and analyzed, inspectors' reports are still handwritten and slow to work their way through the compliance system, and the system for managing imported products cannot communicate with customs and other government systems," the report stated.

The agency often misses significant product arrivals because its computers are so poor that they cannot distinguish between shipments of road salt and those of table salt, the report said.

The Institute of Medicine, the nation's most prestigious scientific advisory organization, concluded last year that the agency's system for ensuring the safety of drugs needed an overhaul. Recent legislation enacted some of the institute's recommendations.

More hearings regarding the F.D.A.'s oversight of food are in the offing, including one in the Senate on Tuesday. The report concluded that the "F.D.A.'s ability to provide its basic food system inspection, enforcement and rule-making functions is severely eroded, as is its ability to respond to outbreaks in a timely manner."

Garret A. FitzGerald, a pharmacologist from the University of Pennsylvania and adviser to the authors, said the report was raising an alarm because "this is a crisis." Dr. FitzGerald pointed to a series of food and drug scares that have demonstrated how little oversight the F.D.A. provides.

He blamed a "cabal of Congressional majorities and presidential administrations that has serially stripped the agency of assets."

Correction: December 6, 2007

An article on Saturday about an advisers' report critical of the Food and Drug Administration misstated the date that the report was made public. It was posted on the agency's Web site last Thursday, not on Friday.

Budget Justification

A. Implementation of Critical Path ($50M/yr) for first two years with significant increase in yr 03 to increase external collaborations.

B. Drug Safety $350M per year, plus $210M = $560M

Source: IOM Report on Drug Safety September, 2006. Reviewed by CDER, Surveillance/Biostatistics Working Group of the Science and Technology Subcommittee of the FDA Science Board who agreed with the general high level recommendations and additional breakdown as follows: Some of the major items included in this total figure are an assumed $100M annual funding for FDA research and $110M per year to fund a fully operational active surveillance system that several Chapter 4 recommendations [Science of Safety] seem to speak to. This figure also includes an estimate of approximately $25M to implement new regulatory authorities [per Chapter 5]. This total also includes rough estimates for miscellaneous other recommendations. Then an estimated $60M for epidemiology contracts and $150M to establish public/private partnership as outlined in Chapter 7 of the IOM report.

C. Emerging Science with Emphasis upon Genomics $50M (31.95M genomics plus 15M for other emerging sciences)/yr first two with concomitant increases for other emerging areas of science

SUMMARY OF RECOMMENDATIONS AT A GLANCE

Recruit and retain staff		
Laboratory Personnel	15	@$150K per year = $ 2.25 M
IT infrastructure	3	@$100K per year = $ 0.30 M
Review staff	30	@$130K per year = $ 3.90 M
Regulatory review staff	35	@$140K per year = $ 4.90 M
Administrative and support	12	@$ 50K per year = $ 0.60 M
Finish and equip lab space	50,000 ft^2	@$300/sq. ft. $15 M
CRADAs, especially for post-launch safety monitoring	10	@$500K per year = $ 5 M

- Estimated Total Cost to implement recommendations, per year = $50.00 Million

D. Food Safety $400M

Source: FDA Coalition Data but Reviewed by the CFSAN/CVM Working Group of the Science and Technology Subcommittee of the FDA Science Board Who Agreed were reasonable estimates. The Coalition increased their original estimate from $250M as outlined below to $400M which was also supported by the Subcommittee working group. The later includes $150M to strengthen Imports.

General principles:

- All five areas are high priorities, and funding should remain proportionate among them
- Funding between CFSAN and ORA should remain proportionate to existing ratio of 1/3 CFSAN and 2/3 ORA.

Priority Areas for FDA Funding for Foods Program:

Totals: $250 million for FDA [CFSAN: $90 million; ORA $160 million]

1. Enhance food safety by filling gaps and increasing inspections and compliance: FDA funding would provide for modernized food safety standards for fresh produce and other raw foods and increased inspections, compliance, and rapid outbreak response. Increase focus on imports

Added funds needed: CFSAN: 50 million ORA: 160 million

Focus Areas

- Fresh Produce and Other Raw Foods (e.g., eggs, seafood).
- Modernize food safety standards.
- Develop and implement inspectional programs to audit industry compliance.
  CFSAN: 30 million ORA: 60 million
- Imports.
- Increase the staffing at FDA's import districts to meet the demands of a more robust import inspection program.
- Improve information technology that will aide in risk ranking of various ingredients, products and sources.
- Enhance rapid inspection methods for imports.
  CFSAN: 10 million ORA: 60 million
- Infrastructure.
- Enhance existing laboratory infrastructure, with increased staffing and adequate equipment, to provide for higher volume of product testing, from both domestic and import inspection programs.
- Enhance real-time testing methodologies to increase speed and accuracy.
- Enhance information technology systems needed to track and prioritize activities.
  CFSAN: 10 million ORA: 40 million

2. **Risk Assessment**: FDA funding would enable FDA to lead multi-stakeholder task force (FDA, EPA, academics, industry, consumer groups) to undertake a project to develop a risk prioritization model and assessment for contaminants found in food at low levels.

Added funds needed: **CFSAN: 15 million, for Office of Plant and Dairy Foods and related functions**

Focus Areas

- Develop a predictive toxicology model that indicates the relative risk associated with a given chemical when found in food.
  a. Model would take into account chemical's structure activity, known toxicology, exposure or ingestion estimates, etc.
  b. Allows FDA and industry to focus mitigation resources on compounds that affect health.
- Conduct additional microbial risk assessments to better assess relative risk of microbial contaminants.
- Develop a risk prioritization model that includes both chemical and microbial hazards.

3. **Advance safe new products and technologies for foods:** FDA funding would ensure that new food additives, new food contact substances, and new biotechnology varieties receive a thorough and efficient review by FDA so consumers can benefit from their introduction into foods.

Added funds needed: **CFSAN: 5 million, for Office of Food Additive Safety and related functions**

Focus Areas

- Increase staffing for food additive petitions, food contact substance notifications, GRAS (Generally Recognized as Safe) notifications and biotechnology consultations, as well as review the safety of existing ingredients
- Enhance computerized support for food additive program, including electronic submissions;

4. **Promote health and wellness:** FDA funding would ensure that the agency is playing a vigorous role in helping consumers make sound food choices to meet today's dietary recommendations. This would involve reviewing new health-related claims in a thorough and timely way, as well as adapt the food label to consumers' nutritional needs.

Added funds needed: **CFSAN: 15 million for Office of Nutritional Products, Labeling and Dietary Supplements, and related functions.**

Focus Areas

- Undertake major recruitment program for scientific experts nutrition and related fields, to regain national and international
- Increase regulatory staffing as needed to modernize the food label to align with the Dietary Guidelines and My Pyramid.
- Increase staffing to review health claim, nutrient content claim, and related petitions, as well as labeling complaints, in a timely way.
- Increase staffing to improve public education on making sound dietary choices and combat the rising problem of obesity.

5. **International harmonization:** In today's ever-increasing international trade in food products, FDA funding would ensure that FDA continues as a world leader in promoting international harmonization and providing science-based standards for international trade.

Added funds needed: **CFSAN: 5 million**

Focus Areas

- Increase staffing, expertise and travel budget for full and vigorous participation in Codex and Codex-related activities for harmonizing international standards for food.
- Increase staffing, expertise and travel budget needed to attending international conferences on emerging scientific issues.

E. IT BUDGET RECOMMENDATIONS

Source: Developed by IT Science and Technology Subcommittee Working Group of FDA Science Board.

The current IT budget is clearly insufficient to support the FDA's mission. For example, over 80% of the FDA network servers are more than 5 years old and thus are in service beyond the recommended life expectancy of such machines. If even such fundamental IT infrastructure components are inadequate, how can the FDA be expected to invest in the capability to manage emerging risks such as the new sciences (panomics, wireless healthcare solutions, nanotechnology, medical imaging), bioterrorism threats, remote sensing networks to scale the monitoring of manufacturing or prototypes for complex global electronic product code architectures to support anti-fraud activities? As a simple example of the consequences of an unstable technology infrastructure, the FDA's participation in the national E.Coli O157 outbreak in 2006 was hampered by outages in the FDA email system that is dependent on the outdated FDA technology infrastructure.

Critical IT programs at the FDA that are responsible for planning and implementing scalable data exchange capabilities, e.g. the enterprise architecture activity which is responsible for the standardization of technology across the

whole agency and the data standards activity which defines how the FDA and its stakeholders will exchange data, are grossly understaffed for an agency the size of the FDA.

The overall IT budget for the FDA is 200M dollars compared to 500M for the CDC. While the FDA has a total of 12,000 staff and the CDC has a total of 14,000 staff. In many ways, the IT operational activities of the two agencies are similar. Specifically, each agency must manage complex scientific data, set data sharing standards, support internal scientific operations and support extramural capability to reduce risk to the public. However, the CDC average IT expenditure per staff person is approximately 35,000 dollars compared to 16,000 dollars at the FDA. Not only must the FDA deliver capability in the terrorism preparedness and response arena that is very similar to that at the CDC but the FDA must also regulate approximately 1 trillion dollars worth of consumer goods or about 25 cents on every consumer dollar expended in this country. It seems to follow that its IT budget should easily surpass that of its sister agency, the CDC, however, as we can see the FDA IT budget is only about 40% of the CDC IT budget.

While the IT staff to total staff ratio approaches industry benchmarks at 5.8/100, it is important to recognize that these benchmarks do not take into account either the complexity of the FDA scientific mission nor does it take into account the need for the FDA to support the development of national/international information sharing capability.

The FDA must invest in the development of large-scale, sustainable data sharing infrastructures to support clinical trials and pharmacovigilance, quality activities, registration activities, and manufacturing life-cycle activities (e.g., electronic product coding to prevent manufacturing fraud). These are expensive, but critical, investments. As benchmarks, we can examine other government investments. Examples of major CDC IT investments (estimated costs for 2006-2008 from http://www.cdc.gov/od/ocio/CDC_IT_Strategic_Plan_FY_08-12.pdf) include the following: BioSense ($164 million), National Electronic Disease Surveillance Systems (NEDDS) ($75 million), and the National Select Agent Registry ($20 million). The cost estimates for these CDC systems do not include the tens of millions of dollars already invested in them over the previous 3–5 years. DHS is investing in the National Biosurveillance Integration System (NBIS) ($15 million for first year of development), and the National Cancer Institute is investing in the Cancer Biomedical Informatics Grid (CaBIG) ($20 million/year for first three years).

The FDA must have a sizable budget to support extramural activities that accelerate the development of health information exchanges to support clinical trials and pharmacovigilance. These entities will be external to the FDA and will be owned by the health care providers and payers. However, it is critical that the FDA establish the necessary data and information standards as well as

consolidated repositories that store data for clinical trials and pharmacovigilance so that the independent health information exchanges can aggregate data.

As we consider recommendations for the FDA IT budget we must recognize that each of the FDA emerging risk areas will need a similar sized investment to prepare the agency to regulate these fast developing fields including: panomics, wireless healthcare devices, medical imaging, and nanotechnology. The investment must cover the cost of the development of a team, analysis of the emerging risk, and development of an information technology capability to support the regulatory role of the FDA for the new science area.

Starting from the base of 200M dollars that has clearly been insufficient to support the regulatory science and regulatory services that the FDA must execute, the FDA must receive the following additional IT investments to support the recommendations above.

Recommended Additional IT Funding Above Current Baseline

IT Investment Area	Funding per Year
Critical Information Supply Chains	45 million
New Science and Emerging Risks	50 million
Food Safety	70 million
Technology Infrastructure	15 million
IT Best Practices	5 million
Collaboration Platforms	10 million
Legislative	3 million
Total	198 million

Appendix B

The State of Science at the Food and Drug Administration

By Peter Barton Hutt•

Introduction

Science at the Food and Drug Administration (FDA) today is in a precarious position. In terms of both personnel and the money to support them, the agency is barely hanging on by its fingertips. The accumulating unfunded statutory responsibilities imposed on FDA, the extraordinary advance of scientific discoveries, the complexity of the new products and claims submitted to FDA for pre-market review and approval, the emergence of challenging safety problems, and the globalization of the industries that FDA regulates -- coupled with chronic underfunding by Congress -- have conspired to place demands upon the scientific base of the agency that far exceed its capacity to respond. FDA has become a paradigmatic example of the "hollow government" syndrome -- an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates. For the reasons set forth in this report, Congress must commit to a two-year appropriations program to increase the FDA employees by 50 percent and to double the FDA funding, and then at least to maintain a fully burdened yearly cost-of-living increase of 5.8 percent across all segments of the agency. Without these resources the agency is powerless to improve its performance, will fall only further behind, and will be unable to meet either the mandates of Congress or the expectations of the American public.

Congress and the nation therefore have a choice. We can limp along with a badly crippled FDA and continue to take serious risks with the safety of our food and drug supply, or we can fix the agency and restore it to its former strength and stature. If Congress concludes to fix FDA, however, this cannot be done cheaply. It will be necessary to appropriate substantial personnel and funds to reverse the damage done to FDA in the past two decades.

There should be no doubt about the ability of FDA to absorb and put to good use a 50 percent increase in personnel and a 100 percent increase in funds over two years. Beginning in 1992, four of the FDA Centers have readily accommodated large increases in personnel and funds under user fee statutes and still have major neglected unfunded scientific responsibilities.

• This report was prepared as part of Mr. Hutt's service on the Science Review Subcommittee of the FDA Science Board and reflects his personal analysis and opinion on the matters considered by the Subcommittee. Mr. Hutt is a Senior Counsel at Covington & Burling LLP and teaches a course on Food and Drug law each year at Harvard Law School. He served as FDA Chief Counsel during 1971-1975.

Adequate resources -- both personnel and money -- alone will not be sufficient to repair the deteriorating state of science at FDA. Strong scientific leadership and a new vision to access applicable scientific knowledge and expertise from throughout the government and the private sector are essential to rebuilding the agency's ability to implement its scientific responsibilities effectively. While increasing the FDA staff and doubling the FDA's annual funding by itself will not achieve this objective, without adequate resources even the most creative leadership cannot hope to accomplish what must be done. In short, a substantial increase in resources is a necessary, but not sufficient, requirement to restore the science base at FDA to a level adequate to permit the agency to address its important public health mission.

This report first reviews the overall state of science at FDA in terms of the resources available to the agency as compared with the accumulating unfunded mandates imposed by Congress. It then considers the scientific personnel and resources needed in order to return FDA to a fully-functioning science-based agency in the future.

Lack of Historical Database

It must be emphasized at the outset that analyses of the FDA budget and regulatory activities over the past decades have been hindered, and in many instances have been made impossible, by the lack of a validated FDA historical database. A review of the state of science at FDA should proceed on the basis of well-documented and uniform historical data reflecting the entire spectrum of the agency's budget, personnel, and workload. Because of chronic underfunding of the agency, and the need to focus all available resources on FDA's important public health mission, the agency has never developed a consistent historical database on which adequate analyses can be undertaken. For example, under each of its four user fee statutes the funds and personnel are split among one or more Centers, the Field offices, and various FDA headquarters administrative offices, but FDA has no comprehensive compilation that breaks out these numbers by recipient. FDA's data for the years prior to 1997 do not separate the Centers from the Field force. The agency is unable to break out the personnel and funding levels for cosmetics from the numbers for the Center for Food Safety and Applied Nutrition (CFSAN). The numbers shown in Tables 4 and 5 are therefore a combination of publicly-available data and extrapolations, derived from a variety of sources. The Final Report of the Advisory Committee on the Food and Drug Administration to the Secretary of HHS (May 1991) found the same deficiencies 16 years ago (page 33). In spite of these substantial limitations, however, FDA worked hard to compile sufficient publicly available information to support the development of Tables 4 and 5.

For an agency that traces its origin to 1862 and that has had a federal statutory mandate to regulate the nation's food and drug supply since 1906, this lack of a historical database for budget, personnel, and

regulatory activities is appalling. FDA cannot be managed effectively without understanding where its funds and personnel are allocated as well as the historical trends for its regulatory responsibilities. A science-based approach to regulation requires an infrastructure that can produce adequate data to underpin regulatory planning that will most efficiently and effectively promote and safeguard the American food and drug supply. But it is also the fault of Congress, not just FDA, that such a database does not exist. Congress has failed to provide FDA with personnel and funds adequate to support the information technology and staff essential for such an effort.

Accumulating Unfunded FDA Statutory Mandates

When the Federal Food, Drug, and Cosmetic Act was originally enacted in 1938, the regulatory and compliance issues faced by FDA were comparatively simple and required far less reliance upon science. The issues of adulteration and misbranding could be handled by well-trained Field inspectors located throughout the country. The need for Ph.D.s and M.D.s was modest, and very few were employed by the agency.

There was only one exception. The 1938 Act included pre-market notification (but not pre-market approval) for the safety (but not the effectiveness) of human and animal new drugs. From that modest beginning, FDA's role as gatekeeper to new products has expanded enormously. Through the enactment of a series of landmark statutes beginning in the 1950s and extending through the 1970s, FDA was given a mandate by Congress to review and approve, prior to marketing, the safety of color additives, human food additives, and animal feed additives, and to review and approve the safety and effectiveness of human new drugs, animal new drugs, human biological products, and medical devices for human use. As a practical matter, today no new pharmaceutical product or medical technology can be marketed in the United States without FDA first determining that it is safe and effective for its intended use. In 1990, Congress added pre-market approval for disease prevention and nutrient descriptor claims for food products, and in 1994 it added pre-market review for new dietary supplement ingredients. These unprecedented new responsibilities forever transformed the nature and scope of the agency's workload.

As these and other statutory mandates accumulated, the need for adequately-trained FDA scientific personnel, and the resources appropriate to support them, increased exponentially. With the rapid advance of such scientific disciplines and techniques as analytical chemistry, food technology, recombinant DNA technology, quantitative risk assessment, modern engineering and electronics, the biological sciences, blood and tissue technology, genomics and the other "omics," and nanotechnology -- to name just a few -- FDA has struggled to recruit well-trained scientists and to keep up with new scientific developments in order to maintain a solid medical and

scientific basis for its pre-market review and approval decisions. Without congressional appropriations for increased scientific personnel and funds to support participation in professional scientific meetings and to maintain cutting-edge educational programs within the agency, FDA staff become increasingly isolated and fall behind their counterparts in academia and the regulated industry.

FDA encounters tremendous problems in implementing the burgeoning number of new statutory responsibilities imposed by Congress each year. Table 1 lists the more than 100 statutes that directly impact FDA enacted by Congress only since 1988 -- an average of more than 6 each year. These are in addition to the core provisions of the 1938 Act itself and another 90-plus statutes directly involving FDA that were enacted during 1939-1987. Each of these statutes requires some type of FDA action. Many require the development of implementing regulations, guidance, or other types of policy, and some require the establishment of entire new regulatory programs. Virtually all require some type of scientific knowledge or expertise for the agency adequately to address them. Yet none of these statutes is accompanied by an appropriation of new personnel and increased funding designed to allow adequate implementation. In the history of our country, no other Federal regulatory agency has ever faced such an onslaught of new statutory mandates without appropriate funding and personnel to implement them. Instead, the agency is expected to implement all of these new unfunded congressional mandates with resources that, in the corresponding time, represent at best a flat budget. Not surprisingly, many of the new congressional mandates languish for years or cannot be implemented at all.

For example, in 1994 Congress authorized FDA to establish good manufacturing practice (GMP) regulations for dietary supplements. It took nine years before FDA published proposed regulations in 2003, and four years later the final regulations have just now finally been promulgated. In 1997, Congress required drug manufacturers to notify FDA about the discontinuance of specified drug products. FDA proposed regulations to implement this requirement in 2000, and seven years later has just now promulgated the final regulations.

As another example, it is well-documented that contamination of railroad cars used to transport food and other FDA-regulated products can result in serious health hazards. Congress sought to address this in 1990 by authorizing the Department of Transportation to issue regulations to prevent the contamination of these important products, but DOT eventually determined in 2004 that the expertise for assuring their safety lies with FDA. Congress then enacted a new law in 2005 requiring FDA to establish regulations to assure that food is not transported under conditions that may render the food adulterated. No new personnel or money accompanied this statutory requirement. Substantial scientific resources will be needed if the agency is expected to develop and implement appropriate regulations. As of today, FDA has taken no action to develop these regulations, and has no plans to

do so, because it does not have the requisite scientific resources. This matter is not even mentioned in the 2007 list of the top 150 priorities for CFSAN.

These simple examples illustrate the problems that FDA encounters with the enactment of every one of the new statutory responsibilities embodied in the legislation listed in Table 1. Because they are unfunded mandates, they are often unimplemented mandates.

Just a short while ago, Congress once again enacted an unfunded FDA omnibus statute, the Food and Drug Administration Amendments Act of 2007, that demands substantial FDA scientific resources to analyze and implement. It consists of 11 separate titles, each of which is a comprehensive statute in and of itself, for a total of 155 pages of new regulatory responsibilities -- with no plans for additional appropriated funds or personnel to implement it. Parts of it are funded by user fees, but large parts are not. There are no personnel or funds in the proposed FDA 2008 appropriations to implement the major new programs this new statute mandates. FDA cannot manage this process by tired old slogans like "work smarter." These only insult an already overworked and very dedicated agency staff. The statutes documented in Table 1 -- and particularly the FDA Amendments Act of 2007 -- can only be implemented by diverting the agency's staff from one task to another. To meet the requirements of a new statute, in short, FDA must abandon work on an old one. That is exactly what has been happening at FDA for the past 20 years. The only way to stop the disintegration of FDA's core responsibilities and still maintain the ability to accept new mandated programs is for Congress to appropriate the personnel and funds needed to do both.

Just the congressional consideration of these new statutes through House and Senate legislative hearings -- and the related investigational hearings and letters by other committees and individual members of Congress -- siphon off substantial time of FDA scientists whose expertise is needed to assure that the agency responds fully and accurately. This is unquestionably an important part of our democratic process. But it is also an unfunded major activity that is not accounted for in the budget process even though it consumes thousands of hours of FDA personnel.

In addition to the laws listed in Table 1, which directly require FDA to take action, Congress has enacted a number of statutes of general applicability that place a large administrative burden on FDA in conducting its daily work. Representative statutes of general applicability that require substantial FDA resources for compliance are listed in Table 2. For example, in order to promulgate a regulation, FDA must at a minimum include, in the preamble, not only full consideration of all the substantive issues raised by the regulation itself, but also a cost-benefit analysis, an environmental impact discussion, a federalism evaluation, a small business impact statement, a determination whether there is an unfunded mandate

impact on state or local governments, and an analysis of paperwork obligations. The proposed and final regulations must be reviewed and approved by the Department of Health and Human Services (DHHS) and the White House Office of Management and Budget (OMB). However well-intentioned, these responsibilities place a major burden on FDA and require that scientific resources be diverted from other areas in order to assure compliance. This has led FDA to avoid rulemaking wherever possible and to substitute informal guidance or to take no action whatever on important regulatory matters.

The impact on FDA of just one of these statutes of general applicability can be readily quantified. The Freedom of Information Act requires FDA, along with other federal agencies, to provide documents in the agency's files to the public upon request. This is unquestionably a statute of major importance to the country. Because FDA is the repository of substantial information that is of interest to the regulated industry, academia, and the general public, FDA receives each year more FOI requests than any other government agency except the Federal Bureau of Investigation. Handling these requests places a substantial burden on FDA personnel and funds. To alleviate the cost to FDA, Congress included in the FDA Revitalization Act of 1990 authorization to establish a revolving fund to pay for FOI costs. This has, however, produced only a modest offset to the agency FOI costs. In 2006, FDA received a total of $493,202 in FOI fees, compared to the overall agency FOI costs of more than $11 million. In many instances, it is the scientists and not the support personnel at FDA who must respond to these FOI requests, in order to assure that the correct documents are being provided and that confidential information is not made public. These are the same scientific personnel who have, as their major priority, the review and approval of applications for new products and claims.

The FOI Act requires that FDA determine within 20 days whether it will provide the requested documents, and provide the documents "promptly" thereafter. Because of its lack of funds and personnel, FDA reduced its FOI staff from 123 in 1995 to 88 in 2006. As a result, its backlog of unfilled FOI requests has grown from 13,626 in 2000 to 20,365 in 2007. Some requests date back four years and even longer. The entire system is clearly broken. It cannot be fixed by admonitions that the agency should "do better." It can only be fixed by congressional appropriation of adequate resources devoted to implementing the FOI Act and providing this information to the public.

The statutes of general applicability are not the only directives that have a strong impact on FDA. Every President in the past 40 years has issued one or more Executive Orders that impose additional obligations on FDA. A representative sample is set forth in Table 3. These Executive Orders have the same binding status as a statute and can have as great or greater impact.

For example, President Bush recently issued an Executive Order delegating review of administrative agency guidance to OMB. As noted above, FDA began to issue guidance in the 1970s in order to provide useful information to the regulated industry on important regulatory policy issues, without the formality of promulgating regulations. Now the agency scientists must devote substantial time to determining which guidance fall under OMB review. For each guidance that requires OMB review, the agency must decide whether it has the resources to pursue the matter at all and, if so, what other matters must be abandoned in order to carry this one forward. This is not a criticizism of this Executive Order. But Congress must realize that it entails substantial administrative burdens that require additional personnel and funds to implement.

The combined weight of these unfunded FDA statutes, statutes of general applicability, and Executive Orders is tremendous. Each includes additional responsibilities for the agency without commensurate appropriations for personnel and funds. The result is that, with relatively flat funding and a very large increase in what the country expects from the agency, FDA is falling further and further behind.

These unfunded mandates cascade down on FDA from all sides of the political spectrum. It is not a problem caused by partisan politics. The Administrations of President Clinton and President Bush have been equally unresponsive to FDA's needs. Nor does this report question the justification for these mandates. Rather, it is the undeniable fact that these mandates are unfunded, and thus that FDA lacks the capacity to implement them, that is objectionable. The country cannot withhold the requisite scientific resources from FDA and then complain that the agency is incapable of meeting our expectations.

This disparity between expectations and resources has become increasingly apparent to the public in the past five years. Daily media headlines have focused on safety problems with prescription drugs, medical devices, the food supply, and now pet food as well. Without adequate appropriations, this will not just continue but increase.

The result of this very visible deterioration in FDA resources is a sharp decline in public confidence. Three decades ago, FDA ranked among the most respected federal agencies, with a public confidence rating of about 80 percent. Today, it has plummeted to between 30 and 40 percent:

FDA Public Confidence Rating (Harris Poll)	
1970s	80%
2000	61%
2004	56%
2006	36%

As long as appropriations lag behind public expectations and new responsibilities imposed by Congress, this decline in public confidence can be expected to continue.

At the heart of the problem is the lack of adequate scientific personnel and resources. As noted above, prior to 1970 FDA was primarily a law enforcement agency. Beginning in the 1970s, however, FDA became a modern science-based regulatory agency. With the advent of pre-market review and approval requirements for FDA-regulated products, the bulk of FDA work shifted from the courts to administrative decisions made within the agency. These administrative decisions are almost always based upon science.

The reaction of Congress to the decline of FDA has been to enact further legislation, not to appropriate additional resources. This vastly misperceives the problem. The current reduced state of FDA is not the result of a lack of statutory authority and mandates to foster and protect the public health. It is the direct result of the lack of adequate appropriations of personnel and money to do the job. More statutes only exacerbate the problem.

Scientific research agencies like NIH and CDC have had substantial increases in appropriations over the past two decades but FDA has not. Since 1988, NIH appropriations have increased $22.264 billion and CDC $5.261 billion as compared to $1.096 billion for FDA. The regulated industry has strongly supported higher FDA appropriations, but to no avail. Whatever the reason for this disparity, it is now time for Congress to make up the difference. Today, NIH and the pharmaceutical industry are investing more than $60 billion annually in the search for new lifesaving pharmaceutical products. The important medical and scientific discoveries that flow from our country's preeminent research laboratories will be severely hindered from reaching the patient's bedside unless FDA is given adequate resources.

Need to Leverage Other Scientific Sources

FDA is a science-based regulatory agency, not a scientific research organization. Basic scientific research should be conducted at the National Institutes of Health (NIH), in academia, and in other basic science organizations, not at FDA. But it is vital that FDA have access to that research in order to apply it to the daily regulatory decisions with which it is charged. FDA cannot make well-reasoned decisions on the marketing of new medical technology if it does not have within the agency up-to-date expertise on the science that underpins that technology.

There are also some areas of applied science that are vital to FDA's regulatory mission, such as the development and validation of analytical methods. This form of regulatory science must continue to be supported within the agency.

FDA must take advantage of the programs in other federal agencies that complement the FDA mission and that can, with effective coordination, multiply the impact of what FDA can do alone. For example, there are food safety programs in the Centers for Disease Control and Prevention, the United States Department of Agriculture, State agencies, and the land grant universities. Yet FDA has inadequate appropriations to leverage these resources through a closely-cooperating consortium that could greatly enhance the effectiveness of all the participants.

With increasing technical specialization, FDA must focus on the core areas of scientific expertise that must reside within the agency in order to permit FDA to continue its historic mission, and those areas that can more appropriately be outsourced in order to access technical expertise. No better example of outsourcing exists than information technology. FDA cannot recruit sufficient technicians to allow the agency to design and build a state-of-the-art information technology system by itself, nor should it try to do so. But FDA still needs a core information technology staff to manage the contractors and coordinate the entire effort. To accomplish this for the entire agency will require major new appropriations.

One of the most important issues facing FDA today is the development of a modern active post-market safety surveillance network for drugs, biological products, and medical devices that will establish an early warning system by electronically linking public and private adverse event databases throughout our healthcare system. FDA has struggled with this issue for four decades, lacking both the technology and the appropriations to build an appropriate system. With the advent of current cutting-edge information technology, the technology part of the issue can now readily be addressed. But without substantial immediate appropriations FDA still cannot move forward with a program that is vitally needed to assess the continued safety of our medical products once they reach the marketplace. Congress must recognize this need and act on it promptly, or sit by and witness continuing media revelations of product safety problems.

Because congressional appropriations have failed to support the science base at FDA at an adequate level, in desperation FDA and the regulated industries have sought to fill the gap with user fees -- first for human prescription drugs and biological products, and more recently for medical devices and animal drugs. Even with these non-appropriation funding mechanisms, however, FDA has failed to keep pace with the mandates of Congress and the expectations of the public. Regulatory decisions must therefore be made by an agency that has inadequate scientific personnel and resources. It is not the fault of FDA leadership that this has occurred. It is the fault of the entire country that our most important health agency has been neglected to the extent that the science base on which virtually all of its decisions depend has substantially deteriorated. Unless something is done about it immediately, the ability of FDA to pursue its public

health mission -- to promote and protect the health of the American people -- will become even more tenuous.

Unfinished FDA Safety Programs

The lack of adequate scientific personnel and the resources to support them has had a major adverse impact on important FDA regulatory programs to assure the continued safety of marketed products. For example, on several occasions FDA has established comprehensive reviews of products after they have been marketed, either at the direction of Congress or on its own initiative. Virtually all of these reviews remain unfinished for lack of agency resources.

Color Additives. At the direction of Congress, in 1960 FDA began a review of the safety of all color additives used in food, drugs, and cosmetics since 1906. Today, 47 years later, the lakes of all color additives used in these products still have not yet been the subject of a final safety decision by FDA even though they have been used in marketed products for the past 100 years.

Prescription Drugs. The Drug Amendments of 1962 directed FDA to review the effectiveness of all drugs for which an NDA had become effective solely on the basis of safety between 1938 and 1962. This was implemented by the Drug Efficacy Study Implementation (DESI) program. Today, 45 years later, approximately 20 of these DESI drugs still remain on the market without a final determination of effectiveness.

Nonprescription Drugs. In 1972, FDA established the OTC Drug Review, to review the safety, effectiveness, and labeling of all nonprescription drugs then being marketed. Today, 35 years later, there remain several categories of OTC drugs, representing thousands of separate products, that have not yet been the subject of a final determination under the OTC Drug Review.

Biological Products. Following the transfer of responsibility for the licensing of biological products from NIH to FDA, in 1973 the agency announced that it would conduct a review of the safety, effectiveness, and labeling of all biological products marketed pursuant to licenses issued from 1902 to 1972. Today, 34 years later, the Biologics Review remains only partially completed.

Food Ingredient GRAS List Review. In 1969, President Nixon directed FDA to undertake a comprehensive review of the safety of all food ingredients listed by the agency as generally recognized as safe (GRAS) and thus as marketed without the need for FDA review and approval of safety through promulgation of a food additive regulation. After completing part of the GRAS List Review, FDA abandoned this program for lack of resources and now reviews the safety of marketed GRAS food substances only when specific issues are raised.

Human Food Ingredient GRAS Affirmation. In 1972, FDA established a procedure under which food ingredient manufacturers who marketed their products as GRAS could obtain affirmation from FDA of the safety of these ingredients. Because of a lack of resources FDA abandoned this procedure in 1997 and substituted for it a simple notification procedure under which the agency issues letters stating that the agency has "no questions" but makes no affirmative determination of safety. Today, ten years later, the proposed regulation for this new policy has not yet been promulgated in final form even though the new policy has been fully implemented for human food ingredients.

Animal Feed Ingredient GRAS Affirmation. The 1997 proposed GRAS notification procedure applied to animal feed ingredients as well as human food ingredients. Because of a lack of resources, the Center for Veterinary Medicine (CVM) not only abandoned the GRAS affirmation procedure but declined to implement the new GRAS notification process as well. On request, CVM issues letters stating that the agency has "no objections" but makes no affirmative determination of safety. On the basis of these letters the regulated industry then handles all feed ingredient GRAS issues through the Association of American Feed Control Officials (AAFCO) and individual State agencies.

Review of Pre-1976 Class III Medical Devices. Under the Medical Device Amendments of 1976, all pre-1976 medical devices that are classified by FDA as requiring pre-market approval for safety and effectiveness (Class III) are required to be the subject of a regulation promulgated by the agency either calling for the submission of a pre-market approval (PMA) application or reclassifying the device. Today, 31 years later, up to 15 of these categories of pre-1976 devices -- including post-1976 devices determined to be substantially equivalent -- remain on the market under Class III without an FDA review and decision on their safety and effectiveness.

Food Additive Regulations. In 1977, FDA announced that it would undertake a cyclic review of all food additive regulations to assure that past food safety decisions remained currently justified. Because of a lack of resources FDA abandoned this program in the early 1980s and now reviews the safety of marketed food additives only when specific issues are raised.

Unapproved New Drugs. The DESI program required by the Drug Amendments of 1962, for new drugs that were covered by an NDA between 1938 and 1962, did not extend to drugs that had been marketed without an NDA on the basis of an independent determination by the manufacturer that they were GRAS and thus exempt from the requirement for an NDA. After one of these unapproved new drugs caused serious adverse events that required a nationwide recall, FDA committed to Congress in 1984 that it would review the safety and effectiveness of these products

and take appropriate action. Because FDA has taken action against fewer than ten of these types of drugs since 1984, thousands of unapproved drugs are now being marketed without any type of FDA review of safety or effectiveness and are estimated to represent approximately two percent of all prescriptions.

These represent only a few examples of numerous FDA programs that languish for lack of adequate scientific personnel and funding. They illustrate the problems that the agency faces when congressional appropriations are inadequate to permit FDA to devote scarce resources to important product safety programs.

Lack of Adequate FDA Appropriations

No one outside FDA has enough information about the agency to conduct a zero-based budget analysis for FDA. It is likely that FDA itself has numerous materials that would bear upon such an analysis, but the agency states that it is not able to make those public.

This report therefore pursues a different approach. Attached are tables that present a partial statistical history of the congressional appropriations for FDA personnel and funds for the past 20 years, compiled from publicly-available sources. Tables 4 and 5 cover the 20-year period of 1988 - 2007 (or, where these figures are not available, the most recent years for which they are available). As the last column in Table 5 shows, from 1988 to 1994 FDA's appropriated personnel and funding kept even with its increasing responsibilities and exceeded inflation. The agency's appropriated personnel increased from 7,039 to 9,167 (a gain of 2,128 people) and its funding from $477.504 million to $875.968 million (a gain of $398.464 million). In 1994, however, FDA hit a brick wall. From 1994 to 2007 the agency's appropriated personnel decreased from 9,167 to 7,856 (a loss of 1,311 people), returning it almost to the same level that was appropriated 20 years earlier. FDA's appropriated funding during this time increased by $698.187 million, but this was only about two-thirds the funding needed to keep up with FDA's fully burdened cost-of-living increase of 5.8 percent, compounded yearly. Thus, over the entire 20 years FDA gained only 817 employees -- an increase of 12 percent -- and lost more than $300 million to inflation, while faced with implementing the new statutes listed in Table 1 and the agency's substantial other core responsibilities under the 1938 Act. Confronted with a burgeoning industry as documented in Table 6, it became increasingly impossible for FDA to maintain its historic public health mission.

This report concludes that a substantial increase in appropriations is essential to halt the disintegration of FDA and to allow the agency to regain its former strength and vitality. A 50 percent increase in personnel (FTE) and a 100 percent increase in funds, over a two-year period, is necessary in order to rescue FDA from its current precarious condition.

The FDA appropriations for 2007 provide for 7,856 employees. The recommendation of this report would raise this appropriated level to 9,820 employees in 2008 -- just slightly more than the 9,352 employed by the agency in 1994. The appropriated number of employees would then rise to 11,794 in the following year. This represents only a 64 percent increase from the 7,210 employees appropriated for FDA in 1988, 20 years earlier. Considering just the enormous workload created by the new 100-plus statutes enacted by Congress during this time, this increase is quite modest.

Doubling the funds appropriated for FDA is essential to rebuild regulatory programs that have been decimated over the past 20 years. The recommendation of this report would raise the appropriated funds for FDA from $1.574 billion today to $2.361 billion in 2008 and to $3.148 billion in the following year. Applying FDA's fully burdened cost-of-living factor for the agency of 5.8 percent, compounded annually, for the past 20 years means that $1.475 billion in FDA funding is required just to restore the agency to the same level today as in 1988 ($477.504 million), without consideration of the additional burdens imposed on the agency under the new statutes listed in Table 1. But we need to do much more than just that. For example, substantial funds are needed to construct a nationwide adverse event warning system for medical products and new inspection programs for both domestic and imported products, just three current high priority new programs for the agency. Together just these programs will cost well over $500 million to plan, implement, and maintain. These new funds are vitally needed to make up for years of neglect. The cumulative gap between the funds FDA has needed all these years, and the amount actually appropriated, far exceeds the funding this report is recommending. This recommendation will be sufficient, however, to lift the agency from its present state of disrepair and to allow the rebuilding process to begin.

It must be emphasized that this is not a one-time quick fix. Appropriations for FDA personnel and funding must have indexed increases each year, to prevent another sustained period of deterioration.

The 3,928 new employees that will be hired, and the $1.574 billion in new funds, over this two-year period should primarily be allocated to functions not presently supported by user fees. As discussed in greater detail below, user fees have completely distorted the current FDA budget. The applications review functions for human drugs, biological products, medical devices, and animal drugs have been supported by both indexed appropriations and user fees, while the rest of FDA has stagnated. Accordingly, most of the increased appropriations that we recommend should be allocated to the functions of FDA that have not been supported by user fees, such as CFSAN and the Field force.

FDA regulates an estimated 25 percent of each individual's personal consumption in our country. Each citizen presently pays only $5.21 per year -- about 1.5 pennies per day -- to support the agency. Our proposal would raise this to $10.42 per year, or 3 cents per day. Considering that the products that FDA regulates are essential to sustain life itself, this is a bargain.

Destructive Impact of User Fees

FDA and industry have resorted to user fees to prop up the agency since 1992 only because the pre-market review and approval functions of the agency would collapse without them. In the long run, however, funding FDA by a tax on the regulated industry is not an appropriate solution to the agency's needs and should be abandoned. This approach has clearly contributed to the decline in FDA's public credibility. This report agrees with the Institute of Medicine that Congress should return to providing personnel and funds to FDA by appropriations, not by user fees.

The advent of user fees for prescription drugs and biologics has, in fact, shielded the serious deterioration of FDA science from public view. In 2007 the agency obtained $352 million and 1,519 staff through user fees for new drugs and biological products. But these new resources are specifically limited to the review process for new drug applications (NDAs) and biological license applications (BLAs) and to related safety functions. For example, they do not support the review and promulgation of OTC drug monographs; or the review and decisions relating to DESI and non-DESI unapproved new drugs; or the Critical Path initiative; or post-market compliance review of product labeling and advertising; or the regulation of generic drugs; or Field post-market compliance action to assure the enforcement of FDA GMP requirements; or action relating to counterfeit or illegal internet and imported drugs; or numerous other activities that make important contributions to FDA regulation of pharmaceutical products. Because user fees have focused narrowly on the NDA/BLA review function and the user fee statutes require an annual cost-of-living increase for this function only, the appropriations for the rest of the regulatory process for drugs and biological products have stagnated. Thus, CDER and CBER today are divided into two parts -- the rich (supported by both indexed appropriations and user fees) and the poor (supported by flat or reduced appropriations). This intolerable disparity fails to recognize the importance of all of the parts of these Centers that contribute to the regulation of drugs and biological products.

A close analysis of how user fees actually work reveals an even more pernicious impact on the rest of the FDA budget. Each of the user fee statutes requires that Congress maintain its normal appropriations for the same function, indexed for inflation. At first blush, this makes sense. User fees are intended to add to congressional appropriations, not to replace them. Thus, funding and personnel for the functions of pre-market review and approval of new drugs, biological products,

medical devices, and new animal drugs receive a guaranteed cost-of-living increase each year as well as the user fees. But the impact on FDA as an institution is highly destructive. This system not only creates rich and poor functions within the four Centers that have user fees, but it leaves the remaining two Centers, CFSAN and NCTR, and the FDA Field force absolutely destitute.

This can be illustrated using the FDA budget figures for 2002 and 2005. FDA's total program funding (including user fees) was $1.37 billion in 2002 and $1.62 billion in 2005, broken down in pertinent part as follows:

Total FDA Program Funding ($ Millions)		
	2002	2005
Total FDA Program	1,370.000	1,620.000
Total Review Functions	344.930	637.551
User Fees	181.553	305.288
User Fee Indexing	163.377	332.263
Total Core Functions	854.185	604.035

As a result of user fees the review functions increased substantially, at the expense of the Agency's core functions:

Percent of Total FDA Program Funding		
	2002	2005
Review Functions	25%	39%
Core Functions	62%	37%

In these three years alone, the core functions of FDA -- all of its basic responsibilities for implementing the 1938 Act and its hundreds of amendments -- lost $250 million in funding, an incredible reduction of 29 percent. The core functions dropped precipitously from 62 percent to 37 percent of the total FDA program funding. And since 2005, it has only become worse. This is the real impact of user fees. It documents the systematic dismantling of the FDA's core mission.

Lack of Adequate FDA Personnel

Nor is money alone the answer to the current crisis in FDA science. FDA needs a major increase in scientific personnel and support staff if it is to regain its former strength and stature. Indeed, FDA's most serious deficit during the past 20 years has been the steady erosion in its human capital. Table 5 shows that the total appropriated personnel level in 1988 was 7,039. Today, 20 years later, the appropriated FTE level is 7,856, an increase of only 817 positions, or 12 percent -- and a

loss of 1,311 positions, or 14 percent, since 1994. The avalanche of laws documented in Table 1, together with the increase shown in Table 6 in the FDA-regulated industry, justify the attention of a substantial increase in the agency's scientific personnel.

One example will illustrate this problem. Each year FDA receives an increasing number of reports of adverse events associated with prescription drugs that are submitted by health care practitioners through MedWatch or by the NDA or BLA holder as expedited (for adverse events that are both serious and unexpected) or periodic (quarterly, annually, or at FDA's request):

Total Adverse Event Reports Submitted to FDA			
1996	191,865	2002	322,691
1997	212,978	2003	370,898
1998	247,607	2004	423,031
1999	278,266	2005	464,068
2000	266,978	2006	471,679
2001	285,107		

Even with the 146 percent increase in these reports from 1996 to 2006, FDA has had no increase in personnel to review and evaluate these reports. Simple mathematics shows that in 2006 FDA reviewers spent 40 percent of the time on each report that they spent in 1996. Higher appropriations would not have changed this result. Only a greater number of scientific personnel can return FDA to a more adequate handling of product safety evaluations.

The same scientific deficit occurred with the submission of medical device reports (MDRs) to the Center for Devices and Radiological Health (CDRH). CDRH received 184,222 MDRs in 2005 and 325,742 MDRs in 2006 -- a 77 percent increase in only one year, with no increase in scientific personnel to review and evaluate them.

Science-trained personnel are also essential to audit the conduct of clinical trials submitted to FDA to support applications for FDA-regulated products and claims that require pre-market notification or pre-market approval -- such widely divergent products as artificial sweeteners, automatic defibrillators, new dietary supplement ingredients, blood products, and cancer and AIDS drugs. This biomedical monitoring function of FDA serves the dual purposes of protecting human subjects and verifying the validity of the clinical trial results. Because of its budget constraints, FDA currently conducts only a partial audit of about 1 percent of these trials.

It is a tragedy that, when Congress, other government agencies, and the press uncover deficiencies in FDA regulation, they blame the agency for the problem, not the actual root cause of the agency's

inaction -- the failure of Congress to provide adequate funding and staff to handle the matter. For example, the HHS Inspector General's recent report excoriating FDA for inadequate monitoring of clinical trials drew a headline on the front page of the New York Times that read "Report Assails F.D.A. Oversight of Clinical Trials." Neither the Inspector General nor the New York Times sought to trace the problem to its source and thus to place the blame on Congress, where it really belongs. Every report urging greater FDA action on a particular program should be required to specify what program the agency should discard in order to take on the new one.

Training and mentoring FDA scientific personnel -- both within the agency and through independent professional and academic programs here and abroad -- is an acute need. Application reviewers throughout the agency run the risk of inconsistent or uninformed decisions absent continuing education, coordination, and collaboration. For example, Baysian statistical techniques are encouraged at CDRH but discouraged at CDER. FDA needs a strategic and sustained program of agency-wide in-depth intellectual engagement with its reviewers, not to satisfy idle curiosity but to equip them with the knowledge to confront current issues in health and disease as they are presented in the applications submitted to the agency. Although the explosion of scientific knowledge over the past 20 years seems daunting enough, it promises to be even more overwhelming in the next 20 years. FDA must prepare for it. Without the personnel and funds to develop and implement such a program FDA reviewers and their decisions will be poorly informed and the public health will be poorly served.

Attracting and retaining qualified scientists is a serious problem at FDA. The regulated industry almost always offers higher pay and benefits than FDA for entry level personnel. And once FDA trains its scientists, their expertise in FDA regulatory practice and policy makes them even more valuable to the industry. Confronted with frustration from the working conditions at FDA -- too few personnel and too little money -- and the opportunity for higher pay and better working conditions in industry, it is not surprising that FDA's attrition rates for scientists are higher than in other federal scientific agencies. This can be addressed by FDA only through congressional appropriations of additional personnel and funds.

The type of project planning undertaken by scientific research organizations cannot be rigorously implemented by FDA. In addition to its routine regulatory responsibilities, FDA is a crisis management organization. At any moment, FDA scientists both in Washington and in the Field must be prepared to ignore their established priorities and statutory deadlines in order to confront safety issues raised by food contaminated with pathogens, animal feed and pet food with chemical contaminants, fish with antibiotics, malfunctioning medical devices, serious adverse events associated with prescription drugs, BSE in cattle, and a host of other problems for which the agency is responsible. Because these issues are broadcast instantly throughout

the country through the electronic media, Congress and the public expect immediate answers and action from FDA. It is essential that the agency always have a critical mass of scientific expertise adequate to respond knowledgeably and effectively. It is also essential for the country to understand that there are some questions for which there are no quick and easy answers and that this is no reflection on the dedication or ability of the FDA scientists. But to handle these communication crises, FDA has an inadequate staff throughout the agency.

Disintegration of CFSAN

The science functions within the FDA Center for Food Safety and Applied Nutrition (CFSAN) have been hit particularly hard. In the 15 years from 1992 to 2007, CFSAN suffered a reduction in force of 138 people, from 950 to 812, or 15 percent of its staff. During the same period, Table 1 shows that Congress enacted new legislation creating large new responsibilities for CFSAN, all of which required substantial scientific expertise for implementation. CFSAN has been expected to implement such complex statutes as the Nutrition Labeling and Education Act of 1990, the Dietary Supplement Health and Education Act of 1994, the FDA Modernization Act of 1997, the Food Safety and Security Amendments of 2002, the Food Allergen Labeling and Consumer Protection Act of 2004, and the Sanitary Food Transportation Act of 2005, and most recently the Dietary Supplement Adverse Event Reporting Act of 2006 and the Food Safety Amendments of 2007 -- to name just the most important unfunded food statutes enacted during this period -- while facing a loss of 138 people.

This disintegration of the FDA food regulation function has continued unabated over the past quarter century. Sixteen years ago the Final Report of the Advisory Committee on the Food and Drug Administration to the Secretary of HHS (May 1991) identified the same problems (Appendix D, page 1):

> There are deep concerns about the viability of the foods program and the lack of agency priority for food issues. Decline in resources and program initiatives during the past 10-15 years indicate a lack of agency management attention and interest in this area, although public interest in, and concern for, an effective food program remain high.

The status of CFSAN today is far worse than it was in 1991.

Dietary supplements receive far too little attention within CFSAN, because of the lack of adequate funding for scientific personnel. Following the enactment of the Dietary Supplement Health and Education Act of 1994, the dietary supplement industry has experienced a major increase in sales. From 1990 to 2005, the annual sales of dietary supplements increased from $5 billion to over $20 billion. Because the manufacturers of these products are authorized by law to petition FDA for approval of disease prevention claims, and

to make claims relating to the impact of their products on the structure or function of the human body without requesting FDA approval, it is essential that CFSAN employ physicians and scientists who can monitor these claims and recommend regulatory action where the claims are not justified. But during the time that these claims were becoming more prevalent and prominent following enactment of the Nutrition Labeling and Education Act of 1990 and the Dietary Supplement Health and Education Act of 1994, and the landmark First Amendment case of Pearson v. Shalala in 1999, Congress reduced the personnel responsible for reviewing and regulating these claims by 145 people. It is impossible for CFSAN to fulfill its statutory obligations under these conditions. The scientific personnel at CFSAN cannot "do more with less." They can only do less with less, and that is in fact what has happened.

Within CFSAN, the Office of Cosmetics has suffered even more than CFSAN itself. At one time, the cosmetic regulation function within CFSAN was funded adequately and had a robust regulatory program. These were the appropriations during 1972 - 1977 for the regulation of cosmetics:

Appropriations for Regulation of Cosmetics ($ Millions)	
1972	$1.308
1973	$1.991
1974	$2.425
1975	$2.286
1976	$2.581
1977	$2.790

Approximately 60 FTE were engaged in the regulation of cosmetics at CFSAN during this period. By 1980, however, the appropriations were reduced to $1.855 million and CFSAN had 39 personnel devoted to cosmetics. In 1997, this was reduced to 26 personnel. In 2007, there are only 14 staff employed at CFSAN to regulate cosmetics, supported by a minimal $3.5 million in funding.

FDA has long stated that cosmetics are the safest products that the agency regulates. Nonetheless, there are important regulatory issues relating to cosmetics that deserve adequate attention by FDA. A total of 14 staff personnel is clearly insufficient for a credible regulatory program for cosmetics, an industry with more than $60 billion in annual sales. Just to keep up with inflation since 1977, the appropriations for cosmetics must be at least $10 million in 2007, instead of the $3.5 it has received, and the personnel level must be restored accordingly

Deterioration of the FDA Field Force

The review and approval of product applications is not the only FDA function that requires scientific knowledge and training. FDA inspectors in the Field force -- in both domestic and foreign manufacturing establishments and at our ports of entry -- must daily make scientific evaluations of the FDA-regulated products that they encounter. In the past 35 years, however, the decrease in FDA funding for inspection of our food and drug supply has forced FDA to impose a major reduction in the number of inspections. For example, the following table documents the decline in Field inspections of food establishments:

FDA Inspection of Foreign and Domestic Food Establishments			
1973	34,919	1995	5,741
1975	22,471	2000	7,204
1980	29,355	2005	9,038
1985	12,850	2006	7,783
1990	7,077		

This represents a 78 percent reduction in food inspections, at a time when Table 6 documents that the food industry has been rapidly expanding. FDA conducted twice the number of foreign and domestic food establishment inspections in 1973 (34,919) than it did for all FDA-regulated products in 2006 (17,641). This is what happens when Congress fails to authorize sufficient personnel and appropriations for FDA adequately to implement the agency's core statutory mandates.

The reduction in FDA establishment inspections has hit hardest at food and cosmetics. The law requires that FDA inspect every drug and medical device establishment in the United States at least once every two years. Although FDA repeatedly violates this unfunded statutory mandate, the agency does inspect drug and medical device manufacturers more frequently than food and cosmetic manufacturers. FDA estimates that the Field inspects food manufacturers at most once every ten years and cosmetic manufacturers less frequently. The agency conducts no inspections of retail food establishments and only limited inspections of food-producing farms, except in emergencies.

As a result of its lack of resources, the agency has recently announced that it will rely more upon State food and drug inspectors to fill the void. Because of similar budget constraints at the State level, however, and the variable number of inspectors in the individual States, this policy will produce useful assistance only in a few large States and is not an adequate substitute for regular FDA inspections throughout the country. For that reason, FDA Field officials recently truthfully and accurately testified before Congress that the agency is failing to meet its statutory obligations and is doing a poor job in

implementing the current law. They are to be commended for their candor and honesty.

At the same time, importation of food into the United States has been exploding. During 1990-2005, imports of FDA-regulated products increased from 2 million to 15 million lines per year -- an extraordinary 650 percent increase -- the majority of which are food. We now import more than 15 percent of our food supply. To meet this crushing tide of food imports, along with inspections of the domestic food industry, Congress appropriated only a 13 percent increase in Field personnel. With inadequate resources to handle these burgeoning imports, FDA now conducts a brief visual review of less than one percent of imports and conducts an actual physical examination for less than a tenth of one percent.

Realizing that this was untenable, in 2002 FDA proposed a science-based plan to reinvent food import regulation through use of scientific risk assessment and risk management techniques. Because it was estimated to cost $80 million, however, the proposal did not make it through the Federal budget process. The resulting crises in adulterated and misbranded imported food during the past year have been the direct result of that decision. The $80 million price tag for a new science-based import program -- which will cost at least $100 million today -- is dwarfed by the hundreds of millions of dollars lost as a result of the failure to implement this program.

In his recent Executive Order announcing an Interagency Working Group on Import Safety, President Bush stated that the current system must be fixed "within available resources." The truth is that the system cannot be fixed "within available resources," but this answer is not politically correct and thus undoubtedly will not make it through the political process. Unless we are willing as a country to appropriate at least $100 million for the scientific personnel and analyses needed to devise and implement a new food import system, we will retain the antiquated version we have now and will continue to witness the crises that we have seen in the past year.

FDA needs to develop the same type of science-based inspection program for domestic establishment inspections that it developed (but was not allowed to implement) for import inspections. Implementation of an adequate domestic inspection program would, of course, cost substantially more than the projected cost of the import inspection program. Without such a science-based plan, and the means to implement it, the country will continue to experience increased food safety problems -- such as the episodes of pathogens in spinach, lettuce, tomatoes, and peanut butter, and botulism in canned food, during the past year.

Imports of legitimate products are not the only problem confronting FDA's Field staff. The import of counterfeit drugs -- as well as the manufacture of counterfeit drugs at domestic establishments posing as compounding pharmacies -- are overwhelming the Field inspection personnel. For example, Field inspectors had to trace the source of a million ineffective counterfeit diabetes test strips from the affected patients through 700 pharmacies, eight wholesalers, and two importers, to their ultimate source in China. A substantial increase in the FDA Field force is needed just to handle the growing number of counterfeit products.

Following the attacks on September 11, 2001, Congress appropriated increased funds and personnel for 2002, which allowed FDA to hire 673 new employees to improve its capacity to respond to the potential for terrorist threats and attacks regarding all FDA-regulated products. More than 60 percent of this supplemental appropriation was allocated to food. By 2006, however, all of this funding and personnel had disappeared from FDA appropriations. The number of Field personnel regularly performing inspections of imports fell from 531 in 2003 to 380 in 2006. There are 326 ports in the United States through which FDA-regulated products can enter the country. Obviously, FDA must deploy larger numbers of inspectors in the busiest of these ports, such as New York and San Francisco. Thus, there are many ports where FDA has no inspectors at all.

Because of its increasing responsibilities and its stagnant number of personnel, as well as a lack of travel funds, FDA cannot afford to send many inspectors abroad to investigate problems at their source. In 2000, FDA inspected 887 foreign establishments. By 2006, this was reduced to 738, a cut of 17 percent. Although approximately 80 percent of the active pharmaceutical ingredients used in our prescription drugs are imported from abroad, and foreign imports of drugs and active pharmaceutical ingredients were valued at more than $42 billion in 2006, FDA conducted only 361 foreign drug and biological product establishments in 2006. Only 32 Field inspections were made in India and 15 in China, the two largest sources of pharmaceutical exports to the United States. Millions of shipments of FDA-regulated products are imported into the country each year from foreign facilities that have never been inspected by FDA and, with current appropriations, never will be.

Because of the reduced resources available to the FDA Field force, court enforcement actions have dwindled:

FDA Court Enforcement Cases			
		Criminal	
	Seizure	Injunction	Prosecution
1991	168	21	43
1992	183	31	52

FDA Court Enforcement Cases			
		Criminal	
	Seizure	Injunction	Prosecution
1993	117	23	26
2004	10	13	0
2005	20	15	0
2006	17	17	0
2007	6	12	0

Administrative compliance actions have suffered the same fate:

FDA Warning Letters	
1991	832
1992	1,712
1993	1,788
2004	725
2005	535
2006	538
2007	467

A weakened FDA inevitably leads to weak compliance with the law.

Conclusion

We must all recognize that FDA can increase its attention to high priority issues, or take on entirely new responsibilities, only in the following two ways. First, FDA can divert personnel from other priorities, thus leaving those other areas neglected. This is what happened with contaminated pet food, one of the many areas which have been neglected because of a lack of agency resources. Second, Congress can determine to provide adequate funding for all of the responsibilities that the country expects FDA to implement. But it is clear that, unless Congress adopts this second approach, FDA will of necessity be forced to follow the first.

Science is at the heart of everything that FDA does. Without a strong scientific foundation, the agency will founder and ultimately fail. The scientific resources needed by FDA to carry out its statutory mission cannot be sustained on a minimal budget. Congress must commit to doubling the current FDA funds, together with a 50 percent increase in authorized personnel, within the next two years. From then on, it is essential that the FDA budget at least keep up with inflation and perhaps even more. Another report should be prepared in five years to offer advice on the state of science at FDA at that time and the resource needs that remain.

Table 1 – Statutory History of FDA Regulatory Jurisdiction and Authority 1988–2007

The following compilation of 1988–2007 federal statutes includes only those for which the Food and Drug Administration (FDA) has been specifically delegated administrative responsibility by the Secretary of Health and Human Services and those that specifically direct the Commissioner of Food and Drugs or the agency to participate in federal action. It excludes those statutes that merely renumber the sections in the United States Code or rename the appropriate officials or agencies involved, as well as statutes of general applicability that apply to all federal agencies and are not specifically delegated to FDA. For omnibus statutes that cover more than one FDA-regulated product category (such as the FDA Modernization Act of 1997, the Bioterrorism Act of 2002, and the FDA Amendments Act of 2007), the major components are listed separately.

Year	Statute
1988	Orphan Drug Amendments of 1988 102 Stat. 90 (April 18, 1988)
	Prescription Drug Marketing Act of 1987 102 Stat. 95 (April 22, 1988)
	Pesticide Monitoring Improvements Act of 1988 102 Stat. 1411 (August 23, 1988)

Year	Statute
	Clinical Laboratory Improvement Amendments of 1988 102 Stat. 2903 (October 31, 1988)
	AIDS Amendments of 1988 102 Stat. 3062 (November 4, 1988)
	Food and Drug Administration Act of 1988 102 Stat. 3120 (November 4, 1988)
	Generic Animal Drug and Patent Term Restoration Act 102 Stat. 3971 (November 16, 1988)
	Veterinary Prescription Drug Amendment 102 Stat. 3983 (November 16, 1988)
	Anabolic Steroid and Human Growth Hormone Amendments 102 Stat. 4230 (November 18, 1988)
1989	
1990	National Nutrition Monitoring and Related Research Act of 1990 104 Stat. 1034 (October 22, 1990)
	Sanitary Food Transportation Act of 1990 101 Stat. 1213 (November 3, 1990)
	Congressional Access to FDA Trade Secret Information Amendment 104 Stat. 1388-210 (November 5, 1990)
	Nutrition Labeling and Education Act of 1990 104 Stat. 2353 (November 8, 1990)
	Good Samaritan Food Donation Act 104 Stat. 3183 (November 16, 1990)
	Amtrak Waste Disposal Act 104 Stat. 3185 (November 16, 1990)
	Agricultural Products National Laboratory Accreditation Standards Act 104 Stat. 3562 (November 28, 1990)
	Organic Foods Production Act of 1990 104 Stat. 3935 (November 28, 1990)
	Safe Medical Devices Act of 1990 104 Stat. 4511 (November 28, 1990)
	Combination Products Amendment 104 Stat. 4526 (November 28, 1990)
	Food and Drug Administration Revitalization Act 104 Stat. 4583 (November 28, 1990)
	FDA Freedom of Information Act Fee Retention Amendments 104 Stat. 4584 (November 28, 1990)
	Anabolic Steroids Control Act of 1990 104 Stat. 4851 (November 29, 1990)
	Human Growth Hormone Amendment 104 Stat. 4853 (November 29, 1990)
1991	Nutrition Labeling and Education Act Technical Amendments 105 Stat. 549 (August 17, 1991)
1992	American Technology Preeminence Act of 1991 106 Stat. 7 (February 14, 1992)
	Generic Drug Enforcement Act of 1992 106 Stat. 149 (May 13, 1992)

Year	Statute
	Medical Device Amendments of 1992 106 Stat. 238 (June 16, 1992)
	Methadone Maintenance Amendment 106 Stat. 412 (July 10, 1992)
	American Technology Preeminence Act Amendments 106 Stat. 847 (August 3, 1992)
	Prescription Drug Amendments of 1992 106 Stat. 941 (August 26, 1992)
	Mammography Quality Standards Act of 1992 106 Stat. 3547 (October 27, 1992)
	Prescription Drug User Fee Act of 1992 106 Stat. 4491 (October 29, 1992)
	Dietary Supplement Act of 1992 106 Stat. 4500 (October 29, 1992)
1993	FDA Employee Education Loan Repayment Amendments 107 Stat. 210 (June 10, 1993)
	Nutrition Labeling and Education Act Amendments of 1993 107 Stat. 773 (August 13, 1993)
1994	Nutrition Labeling and Education Act Amendment of 1994 108 Stat. 705 (May 26, 1994)
	Animal Medicinal Drug Use Clarification Act of 1994 108 Stat. 4153 (October 22, 1994)
	Maple Syrup Preemption Amendment 108 Stat. 4154 (October 22, 1994)
	Dietary Supplement Health and Education Act of 1994 108 Stat. 4325 (October 25, 1994)
1995	Edible Oil Regulatory Reform Act 109 Stat. 546 (November 20, 1995)
1996	National Technology Transfer and Advancement Act of 1995 110 Stat. 775 (March 7, 1996)
	Repeal of Saccharin Notice Requirement 110 Stat. 882 (April 1, 1996)
	Repeal of the Tea Importation Act of 1897 110 Stat. 1198 (April 9, 1996)
	FDA Export Reform and Enhancement Act of 1996 110 Stat. 1321-313 (April 26, 1996)
	Export of Partially Processed Biological Products Amendments of 1996 110 Stat. 1321-320 (April 26, 1996)
	Food Quality Protection Act of 1996 110 Stat. 1513 (August 3, 1996)
	Prescription Drug Medication Guide Amendment 110 Stat. 1593 (August 6, 1996)
	Saccharin Study and Labeling Act Extension Amendment of 1996 110 Stat. 1594 (August 6, 1996)
	Import for Export Amendment 110 Stat. 1594 (August 6, 1996)
	Bottled Drinking Water Standards Amendments 110 Stat. 1684 (August 6, 1996)

Year	Statute
	Health Insurance Portability and Accountability Act of 1996 110 Stat. 1936 (August 21, 1996)
	Good Samaritan Food Donation Act 110 Stat. 3011 (October 1, 1996)
	Repeal of Cardiac Pacemaker Registry Requirement 110 Stat. 3031 (October 2, 1996)
	Electronic Freedom of Information Act Amendments of 1996 110 Stat. 3048 (October 2, 1996)
	Comprehensive Methamphetamine Control Act of 1996 110 Stat. 3099 (October 3, 1996)
	Animal Drug Availability Act of 1996 110 Stat. 3151 (October 9, 1996)
	Drug-Induced Rape Prevention and Punishment Act of 1996 110 Stat. 3807 (October 13, 1996)
1997	Food and Drug Administration Modernization Act of 1997 111 Stat. 2296 (November 21, 1997)
	Prescription Drug User Fee Amendments of 1997 111 Stat. 2298 (November 21, 1997)
	Pediatric Drug Testing and Labeling Act of 1997 111 Stat. 2305 (November 21, 1997)
	The Prescription Drug Modernization Act of 1997 111 Stat. 2309 (November 21, 1997)
	The Biological Products Modernization Act of 1997 111 Stat. 2323 (November 21, 1997)
	The Medical Device Modernization Act of 1997 111 Stat. 2332 (November 21, 1997)
	The Food Modernization Act of 1997 111 Stat. 2350 (November 21, 1997)
	The General Provisions Modernization Act of 1997 111 Stat. 2356 (November 21, 1997)
1998	Food Safety Research and National Conference Amendments 112 Stat. 606 (June 23, 1998)
	Biomaterials Access Assurance Act of 1998 112 Stat. 1519 (August 13, 1998)
	Mammography Quality Standards Reauthorization Act of 1998 112 Stat. 1864 (October 9, 1998)
	Animal Drug Combination Ingredient Amendment 112 Stat. 2681-30 (October 21, 1998)
	Methamphetamine Trafficking Penalty Enhancement Act of 1998 112 Stat. 2681-759 (October 21, 1998)
	Antimicrobial Regulation Technical Corrections Act of 1998 112 Stat. 3035 (October 30, 1998)
	Repeal of Annual Report on Radiation Control for Health and Safety Program 112 Stat. 3285 (November 10, 1998)
1999	Healthcare Research and Quality Act of 1999 113 Stat. 1653 (December 6, 1999)

Year	Statute
2000	Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000 114 Stat. 7 (February 18, 2000)
	Autoimmune Diseases Amendments 114 Stat. 1153 (October 17, 2000)
	Research in Children Amendment 114 Stat. 1167 (October 17, 2000)
	Drug Addiction Treatment Act of 2000 114 Stat. 1222 (October 17, 2000)
	Methamphetamine Production, Trafficking, and Abuse Act of 2000 114 Stat. 1228 (October 17, 2000)
	Rapid HIV Tests Amendment 114 Stat. 1354 (October 20, 2000)
	Medicine Equity and Drug Safety Act of 2000 114 Stat. 1549A-35 (October 28, 2000)
	Prescription Drug Import Fairness Act of 2000 114 Stat. 1549A-40 (October 28, 2000)
	Needlestick Safety and Prevention Act 114 Stat. 1901 (November 6, 2000)
	Human Papillomavirus Education Amendments 114 Stat. 2763A-72 (December 21, 2000)
	Condom Labeling Amendment 114 Stat. 2763A-73 (December 21, 2000)
	Repeal of Saccharin Study and Labeling Act 114 Stat. 2763A-73 (December 21, 2000)
2001	Animal Disease Risk Assessment, Prevention, and Control Act of 2001 115 Stat. 11 (May 24, 2001)
2002	Best Pharmaceuticals for Children Act 115 Stat. 1408 (January 4, 2002)
	Toll Free Number in Drug Labeling Amendment 115 Stat. 1422 (January 4, 2002)
	Catfish and Ginseng Labeling Amendments 116 Stat. 526 (May 13, 2002)
	Food Pasteurization Amendment 116 Stat. 530 (May 13, 2002)
	Food Irradiation Labeling Amendment 116 Stat. 531 (May 13, 2002)
	Accelerated Approval of Priority Bioterrorism Countermeasures Amendment 116 Stat. 613 (June 12, 2002)
	Food Safety and Security Amendments 116 Stat. 662 (June 12, 2002)
	Drug Safety and Security Amendments 116 Stat. 675 (June 12, 2002)
	Prescription Drug User Fee Amendments of 2002 116 Stat. 687 (June 12, 2002)
	Drug Postmarketing Studies Amendments 116 Stat. 693 (June 12, 2002)

Year	Statute
	Medical Device User Fee and Modernization Act of 2002 116 Stat. 1588 (October 26, 2002)
	Rare Diseases Orphan Product Development Act of 2002 116 Stat. 1992 (November 6, 2002)
2003	United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 117 Stat. 711 (May 27, 2003)
	Blood Safety Report Amendments 117 Stat. 902 (August 15, 2003)
	Animal Drug User Fee Act of 2003 117 Stat. 1361 (November 18, 2003)
	Defense Biomedical Countermeasures Amendments 117 Stat. 1680 (November 24, 2003)
	Emergency Use of Medical Products Amendments 117 Stat. 1690 (November 24, 2003)
	Pediatric Research Equity Act of 2003 117 Stat. 1936 (December 3, 2003)
	Abbreviated New Drug Application Amendments 117 Stat. 2448 (December 8, 2003)
	Importation of Prescription Drugs Amendment 117 Stat. 2464 (December 8, 2003)
	Report on Importation of Drugs Amendment 117 Stat. 2469 (December 9, 2003)
2004	Medical Devices Technical Corrections Act 118 Stat. 572 (April 1, 2004)
	Project BioShield Act of 2004 118 Stat. 835 (July 21, 2004)
	Minor Use and Minor Species Animal Health Act of 2004 118 Stat. 891 (August 2, 2004)
	Food Allergen Labeling and Consumer Protection Act of 2004 118 Stat. 905 (August 2, 2004)
	Anabolic Steroid Control Act of 2004 118 Stat. 1661 (October 22, 2004)
	Mammography Quality Standards Reauthorization Act of 2004 118 Stat. 1738 (October 25, 2004)
2005	Patient Safety and Quality Improvement Act of 2005 119 Stat. 424 (July 29, 2005)
	Medical Device User Fee Stabilization Act of 2005 119 Stat. 439 (August 1, 2005)
	Methadone Treatment Amendments 119 Stat. 591 (August 2, 2005)
	Sanitary Food Transportation Act of 2005 119 Stat. 1911 (August 10, 2005)
	Contact Lens Amendment 119 Stat. 2119 (November 9, 2005)
	Stem Cell Therapeutic and Research Act of 2005 119 Stat. 2550 (December 20, 2005)

Year	Statute
	Public Readiness and Emergency Preparedness Act 119 Stat. 2818 (December 30, 2005)
2006	Combat Methamphetamine Epidemic Act of 2005 120 Stat. 256 (March 9, 2006)
	Biomedical Advanced Research and Development Act 120 Stat. 2865 (December 19, 2006)
	Dietary Supplement and Nonprescription Drug Consumer Protection Act 120 Stat. 3469 (December 22, 2006)
	Pandemic and All-Hazards Preparedness Act 120 Stat. 2831 (December 19, 2006)
2007	Food and Drug Administration Amendments Act of 2007 121 Stat. 823 (September 27, 2007)
	Prescription Drug User Fee Amendments of 2007 121 Stat. 825 (September 27, 2007)
	Medical Device User Fee Amendments of 2007 121 Stat. 842 (September 27, 2007)
	Medical Device Amendments of 2007 121 Stat. 852 (September 27, 2007)
	Pediatric Medical Device Safety and Improvement Act of 2007 121 Stat. 859 (September 27, 2007)
	Pediatric Research Equity Act of 2007 121 Stat. 866 (September 27, 2007)
	Best Pharmaceuticals for Children Act of 2007 121 Stat. 876 (September 27, 2007)
	Reagan-Udall Foundation for the Food and Drug Administration Act of 2007 121 Stat. 890 (September 27, 2007)
	Conflicts of Interest Amendments of 2007 121 Stat. 900 (September 27, 2007)
	Clinical Trial Databases Amendments of 2007 121 Stat. 904 (September 27, 2007)
	Postmarket Safety of Drugs Amendments of 2007 121 Stat. 922 (September 27, 2007)
	Food Safety Amendments of 2007 121 Stat. 962 (September 27, 2007)
	Food and Drug Administration Miscellaneous Amendments of 2007 121 Stat. 971 (September 27, 2007)

Table 2 – Representative Statutes of General Applicability that Have a Direct Major Impact on FDA 1935–2006

The following statutes do not specifically name FDA and have not specifically been delegated to FDA for implementation, but they have a substantial impact on the Agency.

Year	Statue
1935	Federal Register Act 49 Stat. 500 (July 26, 1935)
1946	Administrative Procedure Act 60 Stat. 237 (June 11, 1946)
1958	Small Business Act 72 Stat. 384 (July 18, 1958)
1966	Animal Welfare Act 80 Stat. 350 (August 24, 1966)
1967	Freedom of Information Act 81 Stat. 54 (June 5, 1967)
1970	National Environmental Policy Act of 1969 83 Stat. 852 (January 1, 1970)
1972	Federal Advisory Committee Act 86 Stat. 770 (October 6, 1972)
1974	Freedom of Information Act Amendments of 1974 88 Stat. 1561 (November 21, 1974)
	Privacy Act of 1974 88 Stat. 1896 (August 21, 1974)
1976	Government in the Sunshine Act 90 Stat. 1241 (September 13, 1976)
	Freedom of Information Act Amendments of 1976 90 Stat. 1247 (September 13, 1976)
1978	Carcinogen Testing and Listing Amendments 92 Stat. 3434 (November 9, 1978)
1980	Regulatory Flexibility Act 94 Stat. 1164 (September 19, 1980)
	Stevenson-Wydler Technology Innovation Act of 1980 94 Stat. 2311 (October 21, 1980)
	Paperwork Reduction Act of 1980 94 Stat. 2812 (December 11, 1980)
	Bayh-Dole Act 94 Stat. 3019 (December 12, 1980)
1981	Equal Access to Justice Act 95 Stat. 598 (August 13, 1981)
1982	Federal Managers Financial Integrity Act of 1982 96 Stat. 814 (September 8, 1982)
1984	Competition in Contracting Act of 1984 98 Stat. 1175 (July 19, 1984)

Year	Statue
1986	Federal Technology Transfer Act of 1986 100 Stat. 1785 (October 20, 1986)
	Freedom of Information Reform Act of 1986 100 Stat. 3207-48 (October 27, 1986)
1990	Chief Financial Officers Act of 1990 104 Stat. 2838 (November 15, 1990)
	Negotiated Rulemaking Act of 1990 104 Stat. 4969 (November 29, 1990)
1993	Government Performance and Results Act of 1993 107 Stat. 285 (August 3, 1993)
1995	Unfunded Mandates Reform Act of 1995 109 Stat. 49 (March 22, 1995)
	Paperwork Reduction Act of 1995 109 Stat. 163 (May 22, 1995)
	Federal Reports Elimination and Sunset Act of 1995 109 Stat. 707 (December 21, 1995)
1996	Information Technology Management Reform Act of 1996 110 Stat. 679 (February 10, 1996)
	Health Insurance Portability and Accountability Act of 1996 110 Stat. 1936 (August 21, 1996)
	Economic Espionage Act of 1996 110 Stat. 3488 (October 11, 1996)
	National Information Infrastructure Protection Act of 1996 110 Stat. 3491 (October 11, 1996)
1998	Government Paperwork Elimination Act 112 Stat. 2681-749 (October 21, 1998)
	Federal Reports Elimination Act of 1998 112 Stat. 3280 (November 10, 1998)
1999	Federal Financial Assistance Management Improvement Act of 1999 113 Stat. 1486 (November 20, 1999)
2000	Truth in Regulating Act of 2000 114 Stat. 1248 (October 17, 2000)
	Technology Transfer Commercialization Act of 2000 114 Stat. 1742 (November 1, 2000)
	Data Quality Act 114 Stat. 2763A-153 (December 21, 2000)
2002	Customs Border Security Act of 2002 116 Stat. 972 (August 6, 2002)
	E-Government Act of 2002 116 Stat. 2899 (December 17, 2002)

Table 3 – Representative Executive Orders of General Applicability that Have a Direct Major Impact on FDA 1969–2007

The following Executive Orders do not name FDA and have not specifically been delegated to FDA for implementation, but they have a very large impact on the Agency.

President	Executive Order
Nixon	Executive Order No. 11490 (Assigning Emergency Preparedness Functions to Federal Departments and Agencies) 34 Fed. Reg. 17567 (October 30, 1969)
Ford	Executive Order No. 11821 (Inflation Impact Statements) 39 Fed. Reg. 41501 (November 29, 1974)
	Executive Order No. 11921 (Emergency Preparedness Functions) 41 Fed. Reg. 24294 (June 15, 1976)
Carter	Executive Order No. 12044 (Improving Government Regulations) 43 Fed. Reg. 12661 (March 24, 1978)
	Executive Order No. 12174 (Paperwork) 44 Fed. Reg. 69609 (December 4, 1979)
Reagan	Executive Order No. 12291 (Federal Regulation) 46 Fed. Reg. 13193 (February 19, 1981)
	Executive Order No. 12372 (Intergovernmental Review of Federal Programs) 47 Fed. Reg. 30959 (July 16, 1982)
	Executive Order No. 12498 (Regulatory Planning Process) 50 Fed. Reg. 1036 (January 8, 1985)
	Executive Order No. 12512 (Federal Real Property Management) 50 Fed. Reg. 18453 (May 1, 1985)
	Executive Order No. 12600 (Predisclosure Notification Procedures for Confidential Commercial Information) 52 Fed. Reg. 23781 (June 25, 1987)
	Executive Order No. 12612 (Federalism) 52 Fed. Reg. 41635 (October 26, 1987)
George H.W. Bush	Executive Order No. 12689 (Debarment and Suspension) 54 Fed. Reg. 34131 (August 18, 1989)
	Executive Order No. 12770 (Metric Usage in Federal Government Programs) 56 Fed. Reg. 35801 (July 29, 1991)
Clinton	Executive Order No. 12861 (Elimination of One-Half of Executive Branch Internal Regulations) 58 Fed. Reg. 48255 (September 14, 1993)
	Executive Order No. 12862 (Setting Customer Service Standards) 58 Fed. Reg. 48257 (September 14 ,1993)
	Executive Order No. 12866 (Regulatory Planning and Review) 58 Fed. Reg. 51735 (October 4, 1993)
	Executive Order No. 12875 (Enhancing the Intergovernmental Partnership)

President	Executive Order
	58 Fed. Reg. 58093 (October 28, 1993)
	Executive Order No. 12988 (Civil Justice Reform) 61 Fed. Reg. 4729 (February 7, 1996)
	Executive Order No. 13011 (Federal Information Technology) 61 Fed. Reg. 37657 (July 19, 1996)
	Executive Order No. 13083 (Federalism) 63 Fed. Reg. 27651 (May 19, 1998)
	Executive Order No. 13100 (President's Council on Food Safety) 63 Fed. Reg. 45661 (August 25, 1998)
	Executive Order No. 13132 (Federalism) 64 Fed. Reg. 43255 (August 10, 1999)
George W. Bush	Executive Order No. 13327 (Federal Real Property Asset Management) 69 Fed. Reg. 5897 (February 6, 2004)
	Executive Order No. 13422 (Further Amendment to Executive Order 12866 on Regulatory Planning and Review) 72 Fed. Reg. 2763 (January 23, 2007)
	Executive Order No. 13439 (Establishing an InterAgency Working Group on Import Safety) 72 Fed. Reg. 40053 (July 20, 2007)

Table 4 – FDA Appropriations and User Fees Part I FY 1988–FY 2007 ($ Millions)

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
1988								
$ Approp.	89.020	28.110	43.160	8.220	52.440	22.470	17.780	7.630
FTE Approp.	1,359	583	467	117	884	398	287	154
1989								
$ Approp.	99.720	31.495	51.020	9.450	54.920	23.540	17.116	7.336
FTE Approp.	1,339	574	539	135	871	392	269	145
1990								
$ Approp.	111.350	35.17	61.520	11.720	62.560	26.810	21.470	9.200
FTE Approp.	1,418	608	620	155	919	413	285	153
1991								
$ Approp.	134.070	42.330	69.790	13.300	73.340	31.440	24.680	10.580
FTE Approp.	1,584	679	659	165	1,023	459	314	169
1992								
$ Approp.	150.890	47.650	76.050	14.480	81.710	35.020	27.300	11.700
FTE Approp.	1,572	674	718	180	1,107	497	329	177
1993								
$ Approp.	154.052	48.645	82.560	15.721	91.608	37.417	26.612	11.405
FTE Approp.	1,714*	735*	735	194	1,161	522	315	170
$ User Fees	6.800*	2.150*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	N.A.	N.A	N.A	N.A	N.A	N.A	--	--
$Total	160.852	50.795	82.560	15.721	91.608	37.417	26.612	11.405
FTE Total	1,714	735	775	194	1,161	522	315	170

"N.A." (Not Available) means that there is a number for this category but FDA is unable to provide it.

"--"means that there is no number for this category.

"*" means that this number for the category of Human Drugs includes funds or personnel obtained by user fees that were shared with the Center for Biologics Evaluation and Research, the Field, and other parts of FDA but FDA is unable to provide a further breakdown into these categories.

For 1988-1996, the breakdown between the Center and the Field is based on extrapolation from historical data.

1994								
$ Approp.	150.490	47.522	107.180	20.411	111.551	47.808	28.223	12.095
FTE Approp.	1,743	747	882	221	1,169	630	322	173
$ User Fees	30,360*	9.591*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	N.A	N.A	N.A	N.A	N.A	N.A	--	--
$Total	180.850	57.113	107.180	20.411	111.551	47.808	28.223	12.095
FTE Total	1,743	747	882	221	1,169	630	322	173

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
1995								
$ Approp.	109.350	34.526	87.450	16.663	111.485	45.536	29.178	12,506
FTE Approp.	1,277	548	763	191	1,263	568	304	164
$ User Fees	56.290*	17.774*	N.A	N.A	N.A	N.A	--	--
FTE User Fees	317*	136*	N.A	N.A	N.A	N.A	--	--
$Total	165.640	52.300	87.450	16.663	111.485	45.536	29.178	12,506
FTE Total	1,594	684	763	191	1,263	568	304	164
1996								
$ Approp.	153.540	48.484	73.340	13.975	100.600	35.945	25.810	11.061
FTE Approp.	1,476	632	643	161	1,106	497	262	141
$ User Fees	38.660	12.203	25.190	4.801	5.990	5.733	--	--
FTE User Fees	246	105	165	41	30	13	--	--
$Total	192.200	60.687	98.530	18.776	106.590	45.684	25.810	11.061
FTE Total	1,722	737	808	202	1,136	510	262	141
1997								
$ Approp.	139.201	61.878	78.858	17.398	103.207	44.165	25.588	10.628
FTE Approp.	1,287	782	640	221	1,058	561	247	135
$ User Fees	48.764	4.572	25.986	398	4.598	7.851	--	--
FTE User Fees	386	60	204	5	32	16	--	--
$Total	187.965	66.450	104.844	17.496	107.805	52.016	25.588	10.628
FTE Total	1,673	842	844	226	1,090	577	247	135
1998								
$ Approp.	139.201	57.378	78.35	17.744	104.311	39.175	29.375	12.598
FTE Approp.	1,241	784	644	231	1,030	493	264	164
$ User Fees	56.499	5.924	26.095	511	8.653	5.158	--	--
FTE User Fees	404	69	187	5	32	19	--	--
$Total	198.649	63.999	104.668	18.344	107.202	48.503	29.375	12.598
FTE Total	645	853	831	236	1,062	512	264	164
1999								
$ Approp.	139.685	60,738	77.822	17.201	105.553	40.237	30.668	12.585
FTE Approp.	1,130	716	592	199	966	466	254	139
$ User Fees	71.767	6,109	29.031	.311	4.957	8.261	--	--
FTE User Fees	551	59	195	3	32	16	--	--
$Total	211.452	66.847	106.853	17.512	110.510	48.498	30.668	12.585
FTE Total	1,681	775	787	202	998	482	254	139
2000								
$ Approp.	152.194	63.344	87.451	18.592	116.015	41.644	36.471	13.122
FTE Approp.	1,168	670	576	204	988	438	271	135
$ User Fees	88.187	7.509	33.750	834	4.478	8.123	--	--
FTE User Fees	604	67	204	7	30	16	--	--
$Total	240.381	70.853	121.291	19.426	120.493	49.764	36.471	13,122
FTE Total	1,772	737	780	211	1,018	454	271	135

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
2001								
$ Approp.	151.468	67.047	86.215	22.088	121.972	43.334	48.440	15.630
FTE Approp.	1,140	684	561	225	986	442	290	152
$ User Fees	96.995	6.970	36.217	2.710	3.900	8.359	--	--
FTE User Fees	644	67	248	7	30	15	--	--
$Total	248.463	74.017	122.432	24.798	125.872	51.693	48.440	15.630
FTE Total	1,784	751	809	232	1,016	457	290	152
2002								
$ Approp.	178.017	76.683	111.054	27.551	131.466	48.496	55.727	29.916
FTE Approp.	1,122	695	657	237	965	442	323	247
$ User Fees	104.093	5.551	38.287	878	4.919	8.776	--	--
FTE User Fees	658	42	246	7	32	15	--	--
$Total	282.110	82.234	149.311	28.531	136.385	57.272	55.727	29.916
FTE Total	1,780	737	894	242	997	457	323	247
2003								
$ Approp.	188.837	85.236	117.391	27,927	140.429	52.921	57.115	30.544
FTE Approp.	1,159	761	701	246	968	464	341	255
$ User Fees	125.103	4.672	47.116	1.002	14.692	9.243	--	--
FTE User Fees	742	34	274	8	35	18	--	--
$Total	313.940	89.908	164.507	28.929	155.121	62.164	57.115	30.544
FTE Total	1,901	795	975	254	1,003	482	341	255
2004								
$ Approp.	210.828	81.290	96.265	26.089	141.059	50.085	54.430	28.928
FTE Approp.	1,218	725	559	233	971	441	346	246
$ User Fees	162.653	4.821	43.607	1.055	2.879	9.483	1.083	--
FTE User Fees	972	34	247	8	90	13	3	--
$Total	373.481	86.111	139.872	27.144	161.938	59.568	55.513	28.928
FTE Total	2,190	759	797	241	1,061	454	349	246
2005								
$ Approp.	210.481	85.003	96,595	26,514	163.292	51.670	55.360	35.124
FTE Approp.	1,171	666	553	215	970	397	330	241
$ User Fees	185.555	5.095	46.435	1,140	19.865	9.945	7.538	--
FTE User Fees	1,049	32	265	8	134	15	39	--
$Total	396.036	86.098	143.030	27.654	183.157	61.125	62.898	35.124
FTE Total	2,220	698	818	223	1,104	412	369	241
2006								
$ Approp.	217.792	79.919	111.443	27.075	165.207	55.356	53.824	34.756
FTE Approp.	1,176	665	533	197	929	399	321	217
$ User Fees	205.279	5.911	57.466	6.725	24.622	9.856	9.264	--
FTE User Fees	1,100	36	239	10	156	14	54	--
$Total	423.071	85.834	168.909	28.800	189.829	65.212	63.088	34.756
FTE Total	2,276	701	772	207	1,085	413	375	217

Fiscal Year	Human Drugs		Biologics		Medical Devices		Animal Food & Drugs	
	Center	Field	Center	Field	Center	Field	Center	Field
2007								
$ Approp.	230.757	84.381	116.005	28.542	172.258	58.425	58.355	36.394
FTE Approp.	1,186	604	592	190	935	386	324	209
$ User Fees	248.350	6.888	62.069	3.669	29.503	12.734	9.537	--
FTE User Fees	1,134	37	251	11	163	15	54	--
$Total	479.107	91.269	178.074	32.211	201.761	71.159	67.892	36.394
FTE Total	2,320	641	843	201	1,098	401	378	209

Table 5 – FDA Appropriations Part II FY 1988–FY 2007 ($Millions)

Fiscal Year	Food		Cosmetics		NCTR	Total FDA Budget Authority
	Center	Field	Center	Field		
1988						
$ Approp.	53.090	73.310	N.A.	N.A.	24.291	477.504
FTE Approp.	708	1,438	N.A.	N.A.	241	7,039
1989						
$ Approp.	59.310	81.902	N.A.	N.A.	25.545	542.343
FTE Approp.	792	1,585	N.A.	N.A.	239	7,228
1990						
$ Approp.	67.652	93.430	N.A.	N.A.	27.269	600.979
FTE Approp.	841	1,669	N.A.	N.A.	235	7,629
1991						
$ Approp.	77.239	106.660	N.A.	N.A.	31.407	688.392
FTE Approp.	897	1,786	N.A.	N.A.	230	8,267
1992						
$ Approp.	88.421	117.883	N.A.	N.A.	31.097	761.830
FTE Approp.	950	1,782	N.A.	N.A.	239	8,792
1993						
$ Approp.	85.970	118.720	N.A.	N.A.	32.986	805.818
FTE Approp.	913	1,782	N.A.	N.A.	257	8,939
1994						
$ Approp.	89.466	123.548	N.A.	N.A.	34.989	875.968
FTE Approp.	910	1,765	N.A.	N.A.	249	9,167
1995						
$ Approp.	90.887	125.511	N.A.	N.A.	38.349	869.230
FTE Approp.	871	1,719	39	N.A.	247	8,811

Fiscal Year	Food		Cosmetics		NCTR	Total FDA Budget Authority
	Center	Field	Center	Field		
1996						
$ Approp.	84.395	116.546	N.A.	N.A.	30.774	889.527
FTE Approp.	809	1,539	N.A.	N.A.	232	8,459

"NA" (Not Available) means that there is a number for this category but FDA is unable to provide it.

1997						
$ Approp.	78.133	113.050	N.A.	N.A.	31.929	880.743
FTE Approp.	790	1,436	26	8	223	8,354
1998						
$ Approp.	87.758	118.491	N.A.	N.A.	32.189	931.883
FTE Approp.	784	1,455	N.A.	N.A.	218	8,083
1999						
$ Approp.	99.891	135.277	N.A.	N.A.	32.109	985.279
FTE Approp.	784	1,555	N.A.	N.A.	223	7,851
2000						
$ Approp.	124.589	155.115	N.A.	N.A.	36.522	1,048.149
FTE Approp.	830	1,556	N.A.	N.A.	217	7,728
2001						
$ Approp.	125.888	161.616	N.A.	N.A.	36.248	1,009.311
FTE Approp.	879	1,556	N.A.	N.A.	206	7,805
2002						
$ Approp.	143.178	250.078	N.A.	N.A.	39.259	1,354.366
FTE Approp.	924	1,810	30	11	221	8,311
2003						
$ Approp.	147.304	259.520	N.A.	N.A.	40.403	1,398.350
FTE Approp.	950	2,217	29	14	226	8,940
2004						
$ Approp.	144.366	262.686	N.A.	N.A.	39.652	1,401.214
FTE Approp.	910	2,172	29	15	207	8,567
2005						
$ Approp.	152.260	283.257			40.206	1,452.274
FTE Approp.	884	2,059	28	14	187	8,181
2006						
$ Approp.	153.470	285.251	N.A.	N.A.	40.739	1,493.580
FTE Approp.	812	1,962	27	11	190	7,893
2007						
$ Approp.	159.114	297.991	N.A.	N.A.	42.056	1,574.155
FTE Approp.	812	1,896	14	13	190	7,856

Table 6 – Regulated Industry Sales Statistics FY 1988–FY 2007

Fiscal Year	FDA Appropria-tions ($ Millions)	Sales ($ Billions)						
		Human Food	Rx & OTC Drugs	Biological Products	Cosmetics	Animal Feed & Drugs	Medical Devices	Total FDA Products
1988	477.504	563.520	40.848	N.A.	31.800	20.060	29.009	685.237
1989	542.343	600.375	45.055	N.A.	33.900	29.938	31.160	740.428
1990	600.979	649.094	50.683	N.A.	36.000	29.356	33.675	798.808
1991	688.392	677.414	54.870	N.A.	36.900	28.657	35.061	832.902
1992	761.830	682.912	58.159	N.A.	37.900	33.283	35.829	848.083
1993	805.818	710.825	61.675	N.A.	40.300	27.086	37.426	877.312
1994	875.968	742.565	65.086	N.A.	43.200	36.687	38.911	926.449
1995	869.230	766.761	71.760	7.707	45.900	32.090	40.948	957.459
1996	889.527	797.517	79.520	8.743	48.900	44.933	43.406	1,014.278
1997	880.743	838.927	88.753	10.049	51.600	41.255	45.767	1,066.302
1998	931.883	876.419	99.785	12.905	52.500	35.724	46.948	1,111.476
1999	985.279	924.534	115.978	17.136	53.900	36.192	48.755	1,179.359
2000	1,048.149	968.639	132.202	21.130	55.000	35.406	49.496	1,240.743
2001	1,009.311	1,011.876	150.064	26.627	54.400	35.708	49.944	1,302.992
2002	1,354.366	1,050.742	169.552	32.658	54.400	39.334	51.609	1,365.638
2003	1,398.350	1,098.961	186.899	39.239	56.000	44.038	54.733	1,440.631
2004	1,401.214	1,157.534	201.532	46.390	58.200	44.484	55.889	1,517.639
2005	1,452.274	1,230.793	212.520	54.846	61.700	43.177	58.072	1,606.262
2006	1,493.580	N.A.	N.A.	64.009	N.A.	38.303	N.A.	N.A.
2007	1,574.155	--	--	--	--	--	--	--